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**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF NEW YORK**

JANE DOE on behalf of herself and her minor child; JANE BOE, Sr. on behalf of herself and her minor child; JOHN COE, Sr. and JANE COE, Sr. on behalf of themselves and their minor children; JOHN FOE, Sr. on behalf of himself and his minor child; JANE GOE, Sr. on behalf of herself and her minor child; JANE LOE on behalf of herself and her medically fragile child; JANE JOE on behalf of herself and her medically fragile child; CHILDRENS HEALTH DEFENSE, and all others similarly situated,

Plaintiffs,

vs.

HOWARD ZUCKER, in his official capacity as Commissioner of Health for the State of New York; ELIZABETH RAUSCH-PHUNG, M.D., in her official capacity as Director of the Bureau of Immunizations at the New York State Department of Health; the NEW YORK STATE DEPARTMENT OF HEALTH; THREE VILLAGE CENTRAL SCHOOL DISTRICT; CHERYL PEDISICH, acting in her official capacity as Superintendent, Three Village Central School District; CORINNE KEANE, acting in her official capacity as Principal, Paul J. Gelinas Jr. High School, Three Village Central School District; LANSING CENTRAL SCHOOL DISTRICT; CHRIS

Case No.: 1:20-CV-0840 (BKS/CFH)

**CLASS ACTION COMPLAINT**

PETTOGRASSO, acting in her official capacity as Superintendent, Lansing Central School District; CHRISTINE REBERA, acting in her official capacity as Principal, Lansing Middle School, Lansing Central School District; LORRI WHITEMAN, acting in her official capacity as Principal, Lansing Elementary School, Lansing Central School District; PENFIELD CENTRAL SCHOOL DISTRICT; DR. THOMAS PUTNAM, acting in his official capacity as Superintendent, Penfield Central School District; SOUTH HUNTINGTON SCHOOL DISTRICT; DR. DAVID P. BENNARDO, acting in his official capacity as Superintendent, South Huntington School District; BR. DAVID MIGLIORINO, acting in his official capacity as Principal, St. Anthony's High School, South Huntington School District; ITHACA CITY SCHOOL DISTRICT; DR. LUVELLE BROWN, acting in his official capacity as Superintendent, Ithaca City School District; SUSAN ESCHBACH, acting in her official capacity as Principal, Beverly J. Martin Elementary School, Ithaca City School District; SHENENDEHOWA CENTRAL SCHOOL DISTRICT; DR. L. OLIVER ROBINSON, acting in his official capacity as Superintendent, Shenendehowa Central School District; SEAN GNAT, acting in his official capacity as Principal, Koda Middle School, Shenendehowa Central School District; ANDREW HILLS, acting in his official capacity as Principal, Arongen Elementary School, Shenendehowa Central School District; COXSACKIE-ATHENS SCHOOL DISTRICT; RANDALL SQUIER, Superintendent, acting in his official capacity as Superintendent, Coxsackie-Athens School District; FREYA MERCER, acting in her official capacity as Principal, Coxsackie-Athens High School, Coxsackie-Athens School District; ALBANY CITY SCHOOL DISTRICT; KAWEEDA G. ADAMS, acting in her official capacity as Superintendent, Albany City School District; MICHAEL PAOLINO, acting in his official capacity as Principal,

William S. Hackett Middle School, Albany City School District; and all others similarly situated

Defendants.

### INTRODUCTION

1. This lawsuit arises because the above-named defendants and their similarly situated colleagues have adopted policies, procedures, and practices which arbitrarily narrow and place unreasonable burdens on the availability of medical exemptions to the mandatory school immunization requirements for medically fragile children who need them.
2. As a result, hundreds of medically fragile children across New York State have been expelled from school and denied vital services and programming after their medical exemptions written by licensed treating physicians are overruled by school administrators with no medical training.
3. Decades ago, the New York State legislature adopted mandatory school vaccine requirements for the primary purpose of protecting medically fragile children. The theory behind the mandates is that if sufficient numbers of children are vaccinated against a disease, their immunity will create a protective buffer, or “herd immunity,” and thereby prevent disease from reaching those children who cannot take the vaccine or for whom vaccination does not create immunity.
4. Every state in the country including New York, provides a medical exemption to the mandatory vaccine requirements for school admission. New York’s medical exemption is codified in New York Public Health Law §2164[8], which states: “*If any physician licensed to practice medicine in this state certifies that such immunization may be detrimental to a child’s*

*health, the requirements of this section shall be inapplicable until such immunization is found no longer to be detrimental to the child's health. "*

5. On August 16, 2019, acting in his official capacity, defendant Howard Zucker, M.D., issued "*Emergency Regulations to Strengthen Medical Exemption Process for School Vaccinations.*" New York Codes, Rules and Regulations (10 NYCRR §66-1). These regulations were signed into law on December 31, 2019.

6. These new medical exemption regulations, and the policies and practices of the above-named defendants in implementing them, place undue burdens on the availability of a medical exemption for deserving medically fragile children, effectively disabling it for all but an arbitrarily narrow subset of children.

7. First, a new subdivision (l) of section 66-1.1 takes the determination of what "may be detrimental to the child's health" away from the treating physician.

8. Rather than allow physicians to exercise their clinical judgment, the regulations as they are applied narrowly define the allowable reasons for a medical exemption to medical "contraindications or precautions" listed under the Center for Disease Control's Advisory Committee for Immunization Practices guidance ("**ACIP Guidance**").

9. However, the ACIP guidance is not comprehensive and was never intended to serve as a basis for granting or denying medical exemption. The CDC itself has clearly stated that the ACIP guidance is not meant to replace the clinical judgment of a treating physician.

10. Hundreds of additional reasons exist which could put some children at substantial risk of harm as indicated by the long list of precautions and known adverse reactions listed in manufacturers' inserts, the long list of injuries and conditions compensated by the Vaccine Injury

Compensation Program, and the Institute of Medicine reports that clearly and expressly acknowledge subpopulations who have a pre-existing susceptibility to serious adverse reaction.

11. Second, the new regulations give school principals, who do not generally have any medical or legal training, authority to overrule treating physicians.

12. If the principal does not agree or understand how the exemption written by the treating physician fits into the complicated recommendations set forth by ACIP, the regulations allow and encourage them to overrule the treating physician and demand that the medically fragile child either get the contraindicated immunizations or leave school.

13. The new regulations do not require that the school principal consult with any medical professionals before overruling treating physicians and denying a medical exemption.

14. When principals do consult with professionals, the consulting physicians typically have never met the child in question, never conducted a medical examination, have not spoken to the family or gathered the child's or the family's medical history, and have not consulted with the child's treating physicians.

15. Third, the new regulations contain overburdensome requirements for doctors and are being implemented in a manner that deters physicians from writing medical exemptions, even after they have concluded that an immunization is unsafe for the child.

16. Children who have had medical exemptions to immunization for years are now suddenly unable to find a physician willing to submit him/herself to the burdens and intimidation imposed upon physicians who write exemption letters.

17. The number of vaccines that was originally mandated was small and generally tracked pandemics. Under the law today, depending on the region of the state where the child resides, students in any public, private, or parochial school or daycare program must receive at least

twenty six doses of vaccines between birth and the age of eighteen or forego an education. New York Public Health Law § §2164[2][a]. New mandated immunizations are being proposed every year.

18. Many of the mandatory vaccines on the current schedule do not provide protection for anyone but the recipient. This category of vaccines can mitigate symptoms but cannot stop replication and transmission of infectious disease.

19. Even for those vaccines that may provide “sterilizing immunity” and prevent transmission, there is little evidence that the current number of students seeking a medical exemption could pose any significant threat to the community.

20. The potential risk to these children, on the other hand, has been documented by licensed treating physicians as serious enough that the physicians have recommended against one or more of the mandated vaccines.

21. The adoption of the procedures and policies prompted by the NYSDOH Regulations has forced hundreds of New York families to act in a manner contrary to their doctor’s advice about what is safe and appropriate for their child or lose the right to give their child an education.

22. The law is unconstitutional on its face and has the effect of depriving parents and children of a multiple fundamental constitutional rights and even internationally recognized human rights.

23. Since the new regulations were enacted, multiple successful lawsuits have been brought on behalf of individual plaintiffs challenging the arbitrary denial of their child’s medical exemptions. However, hundreds of other children who lack the resources to pursue an individual suit remain unable to get relief.

24. These medically fragile children are the very children the vaccination mandates were primarily enacted to protect.

25. It is well established by peer reviewed science that some children cannot safely receive immunizations. It is vital that children be allowed to follow the advice of their doctors and that their parents maintain the right of informed consent in accordance with the advice of medical professionals that they trust given these known risks.

26. Plaintiffs seek a declaration from this Court affirming that their rights have been violated and entry of a permanent injunction against future infringement on their rights to obtain a medical exemption from immunization.

27. The barriers and burdens placed on the medical exemption process in New York through the new regulations are unconstitutional both on their face and as applied.

#### **JURISDICTION AND VENUE**

28. This is a civil action seeking injunctive relief and damages for the continuing violation of plaintiffs' rights arising under the Fifth and Fourteenth Amendment to the United States Constitution as made actionable pursuant to 42 U.S.C. sec. 1983.

29. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1333(3) and (4) and 2201, 2201(a) and 2202 and 42 U.S.C. sections 1983 and 1988 and supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. §1337.

30. Venue is appropriate as the alleged unconstitutional acts occurred in the Northern District of New York, along with other districts in New York, and some of the plaintiffs and defendants reside in the Northern District of New York.

#### **CLASS ACTION ALLEGATIONS PLAINTIFFS**

31. Plaintiffs, include families of medically fragile children whose medical exemption has been denied or subjected to overburdensome harmful requirements, along with Children's Health Defense, a national not-for-profit organization dedicated to advocating for the safety of children

and whose members include families who are deleteriously impacted by the policies, procedures and practices of the defendants and their agents regarding the medical exemption in New York.

32. Plaintiffs seek certification of this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(2) on behalf of the named plaintiffs and the following class: parents of medically fragile children residing in New York State whose licensed medical providers have indicated or certified that one or more of the vaccines required for school admission in New York might be harmful to the child's health and who have thereafter submitted a medical exemption to a school in New York State and faced unreasonable burdens or denial as a result of the challenged actions of the defendants, their agents and assigns.

33. Named plaintiff assert claims which are common and typical of the claims possessed by other similarly situated persons too numerous to be individually joined in this matter.

34. These common questions predominate over more individualized determinations because the relief plaintiffs seek relates to defendants' practices and policies which affect or may affect each purported class member.

35. The participation of each class member is not required for the efficient and fair resolution of the issues raised herein.

36. Plaintiffs are represented by competent counsel who have experience representing large classes and litigating on their behalves.

37. Proposed class representatives have no conflicts with other class representatives, with class members or counsel. The named class members will fairly and adequately represent the interests of the class.

38. Each named plaintiff possesses a strong personal interest in the subject matter and the primary relief sought is declaratory and injunctive relief from arbitrary and unconstitutional

policies, procedures and practices of defendants which harm all class members in a similar manner.

39. Absent class certification, there is a possibility of inconsistent results affecting class members.

#### **CLASS ACTION ALLEGATIONS DEFENDANTS**

40. Defendants, include the New York State Department of Health, it's agents and assigns, including HOWARD ZUCKER, in his official capacity as Commissioner of Health for the State of New York, ELIZABETH RAUSCH-PHUNG, M.D., in her official capacity as Director of the Bureau of Immunizations at the New York State Department of Health, named and unnamed implementing school districts, along with their agents and assigns, and individually named building principals and superintendents acting in their official capacities as employees of said school districts. Attorneys for the plaintiffs seek certification of a class of defendants pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(2) including all implementing school districts, building principals and superintendents that have implemented the regulations of the New York State Department of Health in a manner which has unreasonably burdened the ability of one or more member of the members of the plaintiff class in this action to obtain medical exemptions for their children pursuant to the advice of their licensed medical providers.

#### **PARTIES**

##### **A. PLAINTIFFS**

41. Plaintiffs are parents and their minor children who have sought medical exemptions from one or more mandatory immunization requirement for school attendance in New York State based on the advice of their treating physicians that such immunization poses unacceptable risks to their children's health, qualifying them for a medical exemption from otherwise required vaccinations.

42. Jane Doe is the mother of John Doe, a fifteen-year-old boy with multiple auto-immune and progressive neurological disease diagnoses who resides with his parents in Greene County, New York in the Coxsackie-Athens School District. John has been denied an education since October 7, 2019 despite having submitted medical exemptions with certifications from two licensed physicians detailing why immunization would not be safe for him.

43. Jane Boe, Sr. is the mother of Jane Boe, a fifteen-year-old girl with multiple diagnosed autoimmune syndromes and health challenges, including autoimmune encephalitis, which causes progressive neurological injury and attacks the brain. Jane and her siblings have all had severe adverse reactions to immunization. Jane's eldest brother died of complications from immunization. Jane has been unable to attend school since January, 2020, despite submitting medical exemptions from three licensed physicians who have indicated that she is at risk of harm and an admission from the reviewing school district doctor that though he felt he had to deny the exemption request, he would not recommend immunizing Jane either. Jane lives with her parents and her surviving brother in the Three Village Central School District in New York.

44. John Coe, Sr. and Jane Coe, Sr. are the parents of Jane Coe (age twelve) and John Coe (age ten), two medically fragile children who live in the Lansing Central School District in New York. Due to a family history of severe reaction to immunization, including two deaths, along with subsequent genetic testing that reveals genetic vulnerability to injury, the children have never been vaccinated. Jane and John have been excluded from school since January 2020 after the medical exemption submitted by a licensed physician and genetic counselor was denied without explanation.

45. John Foe, Sr. is the father of John Foe, an eleven-year-old boy with special needs who suffers from Hirschsprung's Disease, a rare and serious genetic condition. John is so medically

fragile and sensitive to chemicals and many medications that if he needs to take antibiotics, he must be hospitalized first so that medical care can be given to treat the cascade of severe reactions that ensue. On the advice of his pediatrician, John has not been vaccinated since he had a severe reaction to immunization as a baby. He has been excluded from attending public school since September 2019 despite two submissions from his licensed treating pediatrician detailing the severe risks that further immunization poses to him. The family resides in Albany, New York.

46. Jane Goe, Sr. is the mother of Jane Goe, a seventeen-year old suffering from multiple severe diagnosed autoimmune conditions. The family lives in the Penfield Central School District, which denied exemption letters from her treating physician, requiring corroboration from a specialist. The District then denied the subsequent exemption letter written by the chief of endocrinology at the University of Rochester Hospital, stating that Jane would have to submit a third corroborating letter from one of two particular specialists the school district doctor named before the school would consider her exemption request;

47. Jane Loe is the mother of John Loe, a fifteen-year-old severely ill boy who has had medical exemptions from immunization since he was seven years old. John has been unable to attend school since September 2019 despite the submission of medical exemptions written by two highly regarded treating specialists. Before his removal, he attended the school in the South Huntington School District in New York.

48. Jane Joe is the mother of John Joe, a six year old boy with special needs residing in the Ithaca City School District who has had accepted medical exemptions from immunization since he suffered severe anaphylaxis to his hepatitis B vaccine as a baby. John's previously accepted medical exemption was revoked in November 2019, when he was removed from school and

denied any of the extensive services which were promised to him under his Individualized Education Plan with the School District.

49. Plaintiff Children's Health Defense ("CHD") is a national not-for-profit membership organization of parents, advocates for children and attorneys. CHD's mission is and stop environmental harms and to change policies that place children at risk.

50. CHD accomplishes its mission by, among other things: providing resources, training, and information to members to assist them in protecting the rights and health of their children; educating the public and policymakers about the experiences of children with disabilities and their families; and educating members about developments in the federal laws and policies affecting the health of children;

51. CHD has members located across the United States. Membership is open to all persons who are interested in furthering CHD's purposes. The Board of Directors is composed exclusively of CHD members. CHD has active members in New York, including parents of children named in this lawsuit and eligible for class membership in this lawsuit.

52. CHD's members also include attorneys and advocates who represent children with medical exemptions to immunization. Defendant's practices in arbitrarily burdening and limiting the right of families to follow the advice of their medical providers about what is safe for medically fragile children's health has made achieving this mission more difficult, time-consuming, and resource-intensive for these members. These attorneys and advocates have expended time and resources they would have devoted to other work on behalf of medically fragile children in order to respond to requests for assistance concerning the inappropriate denial or constitutionally burdensome requirements placed on the medical exemption process in New York.

53. CHD brings this action on behalf of its active members who have children in the Plaintiff class or who represent a child in the Plaintiff class as an attorney or advocate.

54. Plaintiffs seek to certify a class of all similarly situated families who have been subjected to unconstitutional burdens on the medical exemption application process in New York.

## **B. DEFENDANTS**

55. Defendant Howard Zucker, M.D., (Dr. Zucker), is the duly appointed Commissioner of the Department of Health for the State of New York. He is sued in his official capacity and conducts business in this judicial district.

56. Defendant Elizabeth Rausch-Phung, M.D., (Dr. Rausch-Phung), is the Director of the Bureau of Immunizations at the New York State Department of Health. She is sued in her official capacity and conducts business in this judicial district.

57. Defendant New York State Department of Health (NYSDOH) is the administrative agency in the executive branch of the New York State government. NYSDOH has authority to promulgate rules and regulations pursuant to Article 2 of the State Administrative Procedures Act (SAPA). It conducts business in this judicial district and as a department of the state of New York may be sued pursuant to 42 U.S.C. section 1983 for declaratory and injunctive relief.

58. The Three Village School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

59. Cheryl Pedisich is the Superintendent of the Three Village Central School District and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

60. Corinne Keane is the Principal of Paul J. Gelinas Jr. High School in Three Village Central School and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

61. The Lansing Central School District is a municipal corporation organized pursuant to the laws of the State of New York and may sue and be sued.

62. Chris Pettograsso is the Superintendent of the Lansing Central School District and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

63. Lorri Whiteman is the Principal of Lansing Elementary School and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

64. Christine Rebera is Principal of Lansing Middle School and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

65. The Penfield Central School District is a municipal corporation organized pursuant to the laws of the State of New York and may sue and be sued.

66. Dr. Thomas Putnam is the Superintendent of the Penfield Central School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

67. The South Huntington School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

68. Dr. David P. Bennardo is the Superintendent of the South Huntington School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

69. Brother David Migliorino is the Principal of St. Antony's High School in the South Huntington School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

70. The Ithaca City School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

71. Dr. Luvelle Brown is the Superintendent of the Ithaca City School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

72. Susan Eschbach is the Principal of Beverly J. Martin Elementary School in the Ithaca City School District and is sued in her official capacity for actions and omissions she engaged in as a state actor and under color of state law.

73. The Shenendehowa Central School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

74. Dr. L. Oliver Robinson is the Superintendent of the Shenendehowa Central School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

75. Sean Gnat is the Principal of Koda Middle School in Shenendehowa School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

76. Andrew Hills is the Principal of Arongen Elementary School in Shenendehowa School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

77. The Coxsackie-Athens School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

78. Randall Squier is the Superintendent of the Coxsackie-Athens School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

79. The Albany City School District is a municipal corporation organized pursuant to the laws of the State of New York and it may sue and be sued.

80. Kaweeda G. Adams is the Superintendent of the Albany City School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

81. Michael Paolino is the Principal of William J. Hackett Middle School in Albany City School District and is sued in his official capacity for actions and omissions he engaged in as a state actor and under color of state law.

82. Plaintiffs seek to certify a defendant class of school principals, superintendents and school districts which have implemented the challenged policies and practices against one or more of the plaintiff class.

#### FACTS

83. Defendants and their agents have adopted state-wide policies and procedures that are placing unconstitutional burdens on families of medically fragile children and subjecting them to unjustifiable risk of harm. The individual experiences of the following named plaintiffs are representative of what is happening to hundreds of medically fragile children across New York State.

John Doe

84. John Doe (“**John**”) is a fifteen-year-old boy who resides with his parents Jane Doe and John Doe, Sr. in the Coxsackie-Athens School District in New York.

85. John’s diagnoses include: mitochondrial disorder, hypoglycemia, genetic mutations, environmentally induced porphyria, metabolic and hormonal imbalances, eczema, food and environmental allergies, candida infection, amino acid disorder, heavy metal toxicity, and several autoimmune disorders—including Pediatric Autoimmune Neurological Disorder Associated with Streptococcus (“**PANDAS**”), Irritable Bowel Syndrome (“**IBS**”), thyroid disease, and Gluten-Sensitive Enteropathy.

86. John’s conditions are chronic, incurable and at times debilitating. Before the family found a specialist able to treat him, the family had significant problems maintaining normal routines and John was unable to consistently attend or remain in early childhood programs.

87. When John was four, his parents began seeing a specialist in Massachusetts known to help children with PANDAS. Through years of hard work and vigilant routines by his parents and providers, John has begun to stabilize and regain some measure of health and normalcy.

88. Avoiding triggers, including certain foods, chemicals, and immunizations, has been critical to prevent regression of one or more of John’s auto-immune diseases and in managing his disorders.

89. Following the advice of multiple treating physicians, John has not received any immunizations.

90. On August 23, 2019, John’s parents submitted a medical exemption from John’s pediatrician, Dr. Peter Forman (“**Dr. Forman**”), a licensed New York physician who has been John’s primary care physician for more than ten years. Dr. Forman included a supplemental letter

from Dr. Papanicolaou (“**Dr. Papanicolaou**”), John’s treating physician at the Massachusetts clinic he has attended for eleven years.

91. Both treating physicians have seen John regress into debilitating flare ups of his underlying medical conditions when faced with immune triggers. Both doctors concurred that it was unsafe for John to receive any immunization given his multiple chronic and serious conditions and the risk that immunization could trigger a regression.

92. On September 16, 2019, the school denied the medical exemption based on the opinion of Dr. Stephen G. Hassett (“**Dr. Hassett**”), an emergency medicine physician who acts as a paid consultant to the Coxsackie-Athens Central School District.

93. Dr. Hassett recommended denying the exemption based on his opinion that the letters did not specify how the exemption request qualified under the ACIP contraindications or precautions.

94. Dr. Hassett does not specialize in treating any of John’s medical conditions or even in treating children.

95. Before overriding John’s treating physicians’ recommendations, Dr. Hassett never examined John, called either of his treating physicians or reviewed any of his records other than the exemption form and accompanying letters. In fact, Dr. Hassett refused the mother’s request to speak to John’s pediatrician or review supplementary materials to clarify why the two treating physicians believed that he needed a medical exemption.

96. After the denial, Dr. Forman called Dr. Hassett. During this phone conversation, Dr. Hassett indicated that he had no discretion to hear any supplemental information or support for the exemption and was obligated to follow the strict guidelines set forth by ACIP.

97. On Saturday, October 5, 2019, the family submitted a second medical exemption letter in which Dr. Forman detailed for each vaccine how the child's conditions qualified under the ACIP guidance as a precaution or contraindication.

98. Within twenty-four hours of receiving it, Dr. Hassett denied this second submission.

99. When Jane Doe called regarding the second denial, Dr. Hassett conceded that the exemption letter submitted the second time followed the ACIP guidelines verbatim.

100. Nonetheless, he said he would not "debate" with Jane Doe or provide her with any explanation about his denial and ended the call.

101. To remain in school without a medical exemption, 10 NYCRR § 66-1.1(f)(1) required John to be vaccinated according to the ACIP Schedule for ages 18 years or younger.

102. ACIP's "catch-up guidance" requires E.Y. to receive twenty-four doses of vaccines for ten separate diseases within twelve months.

103. John would have to receive nineteen of the twenty-four doses within a four-week timeline.

104. No safety studies exist evidencing that injecting twenty-four doses of vaccine into the body of a fifteen-year-old child (much less a medically fragile child) within twelve months is safe.

105. Because the family could not risk John's health in this manner, the family did not comply, and the school district expelled John.

106. John has been excluded from participation in classes, in person or online since October 7, 2019. Before his exclusion from school, John was a member of the varsity tennis team and was looking forward to trying out for the varsity volleyball team. He was an active member of several social clubs and was on track to earn a Regents diploma.

107. Now, in addition to being excluded from school and activities, John is not allowed to take any further Regents exams or earn a traditional diploma, and so he will have to forego his Regent's diploma and even his and traditional high-school diploma unless legal relief is forthcoming.

108. The loss of school and related services and socialization has devastated John and harmed him and his family irreparably.

109. The family hired an attorney to file an appeal with the Commissioner of Education on their behalf on or about November 5, 2019. A member of the State Senate sent correspondence to the Commissioner of Education supporting the appeal on or about December 20, 2019. This letter indicated that the New York State legislature did not intend for school districts to have unilateral power to overrule treating physicians. To date, no response to John's appeal has been forthcoming and he remains unable to receive an education at any private or public school or to participate in testing or activities.

*Jane Boe*

110. Jane Boe ("Jane") is a fifteen-year-old girl with multiple diagnosed autoimmune syndromes and health challenges, including autoimmune encephalitis, which causes progressive neurological injury and attacks the brain.

111. Jane lives with her parents, Jane Boe, Sr. and John Boe, and her older brother within the Three Village Central School District in New York.

112. Jane has been diagnosed with autoimmune encephalitis, Postural Orthostatic Tachycardia Syndrome ("POTS"), dysautonomia, and chronic/severe Lyme disease and bartonella.

113. Her health began to significantly deteriorate after her last set of immunizations at age twelve.

114. Jane's siblings also suffered similar severe adverse reactions to immunization. Like Jane, both Jane's brothers developed autoimmune encephalitis and acute neurological neuropsychiatric conditions that were significantly exacerbated by immunization.

115. Much of Jane's childhood has been profoundly impacted by her and her siblings' medical fragility. Jane's middle brother became so ill that he was forced to take a medical leave from middle school to receive medical treatment and homebound instruction. It took several years of continuous treatment for him to regain his health.

116. In 2016, Jane's oldest brother then age eighteen decided to receive the Meningococcal vaccine against medical advice prior to attending his freshman year in college. This, coupled with a flu vaccine and other immune assaults, are believed to have triggered an acute cascade of neurological and other health symptoms that ended with Jane's brother committing suicide in June 2018.

117. Genetic testing shows vulnerabilities that may explain why all three children have developed chronic health conditions after immunization.

118. Jane was not immunized for several years after her adverse reaction at age twelve. In July 2017, she received the TDaP immunization to attend sleepaway camp. After this immunization, Jane's health began to deteriorate again.

119. To date, Jane has received all the mandatory immunizations required of her except for the meningococcal vaccine and booster.

120. Meningococcal vaccines are unable to provide anyone but the recipient with protection.

121. Recent studies confirm that the meningococcal vaccine only has a protective effect on symptoms in the individual who receives the vaccine but cannot stop replication and transmission of disease.

122. Jane's physicians determined that the risks of getting this vaccine far outweighed any potential benefit for Jane.

123. In August 2019, Jane's family submitted a medical exemption from her treating physician, Dr. Laura Bennett ("Dr. Bennett") who is licensed to practice medicine in the State of New York.

124. The Three Village Central School District denied Jane's medical exemption on the advice of the school district's consulting doctor, Dr. Howard Sussman ("Dr. Sussman").

125. Dr. Sussman contacted Dr. Bennett to discuss the impending denial of the medical exemption as written. Dr. Bennett subsequently advised the family that Dr. Sussman stated that he "wouldn't give this child the vaccine either", but the medical exemption wasn't written sufficiently under the new law and recommended she write a new one with "more specific" language. He did not indicate what the "more specific language" should include.

126. Jane's doctor complied with Dr. Sussman's recommendation. On September 17, 2019, Jane's family submitted a second more detailed medical exemption form signed by Dr. Bennett. Dr. Bennett's medical exemption was supplemented by a letter detailing that the reasons for exemption were in line with CDC criteria. She also included a letter from Dr. Nancy O'Hara, a licensed physician and specialist Jane sees in Connecticut ("Dr. O'Hara"). Both physicians noted that Jane was undergoing active treatment and agreed that further immunization could put Jane at risk of serious harm.

127. The school sent the second exemption packet directly to the New York State Department of Health for review.

128. In November 2019, defendant Dr. Rausch-Phung, a non-practicing physician who works for the New York State Department of Health, recommended the school deny the exemption.

129. Without examining Jane, speaking with her two treating physicians, or requesting any supplemental records, Dr. Rausch-Phung wrote that it was in Jane's "best interest" to be immunized with meningococcal vaccine despite the medical concerns and history. She wrote that the death of Jane's sibling, even if it was from an adverse reaction to the vaccine, was not a sufficient reason to grant an exemption.

130. In December 2019, Jane's family submitted a third medical exemption from a third treating physician, Dr. Caroline Hartridge ("Dr. Hartridge"), also a physician licensed to practice medicine in New York. Dr. Hartridge's exemption letter stated that Jane suffered from acute illness, pointing out that acute illness is a listed precaution under the ACIP guidelines concerning meningococcal vaccine and recommending that Jane avoid immunization until her illness was no longer acute.

131. The school district sent the third letter for review at the New York State Department of Health.

132. On March 2, 2020, Dr. Rausch Phung sent a letter allowing a "one month" exemption upon which she asked that the family submit an additional medical exemption form which she would review. The school could not specify whether the month ran from the date of submission of the third exemption letter (December 2019) or the date they received a response from Dr. Rausch Phung (March 2020).

133. The family had to hire an attorney to attempt to negotiate with the school for clarity. The Three Village Central School District refused to consider allowing their principal or superintendent to approve the follow up requests and was unable to provide clarity on whether the exemption in place had to be renewed immediately or in April, and how long it might take to get an answer on the follow up request.

134. Having already lost one child after giving him the meningococcal vaccine against medical advice, the family was unwilling to risk Jane's health by going against their three treating doctors' advice.

135. Jane was being deeply impacted by the uncertainty about her immunization exemption request and has been unable to attend school since January 2020. Jane's parents both work full time. They have been forced to homeschool Jane and have had to spend enormous amounts of money on online programs to try to provide their daughter with an education. Jane's friendships and sense of self-worth have plummeted. Her grieving process intensified, and she has suffered deep depression, anger, and sadness from her exclusion from school.

136. After years working so hard to regain her health, and after the trauma that she and her family have been through, this experience has caused irreparable harm to Jane and her family.

**Jane Coe and John Coe**

137. John Coe ("John"), age twelve, and Jane Coe ("Jane"), age ten, live with their parents, Jane Coe, Sr. and John Coe, Sr. in the Lansing School District in New York.

138. John Coe, Sr.'s brother died from an adverse reaction to his two-month vaccines. The cause of death was documented on the death certificate as having been from immunization and, after a hearing, his estate received compensation from the National Vaccine Injury Compensation Program.

139. Several other family members have suffered severe reactions to vaccines as well.

140. Before his brother died, John Coe, Sr. had a severe reaction to his childhood immunizations. After John Coe, Sr.'s brother died, John Coe, Sr.'s sister was born and despite a delayed immunization schedule, also had a negative reaction to her first childhood

immunization. John Coe, Sr.'s mother, a registered nurse, also had a severe reaction to the flu vaccine. John Coe, Sr.'s cousin also died after administration of her childhood vaccines.

141. John Coe, Sr., and his surviving sibling had medical exemptions from immunization throughout the rest of their childhoods.
142. Upon the advice of medical professionals and considering the family history, John and Jane have never been vaccinated and have had exemptions since they were born.
143. Both children have multiple food, environmental and drug allergies, and precarious health.
144. The family sees a genetic counselor who has identified several genetic mutations and markers that could explain the significant family pattern of adverse reactions and the children's predisposition towards health issues.
145. In addition to a family history of vaccine injury and death, there is a family history of numerous autoimmune and other conditions consistent with the genetic profile of the children.
146. In August 2019, the parents submitted applications for medical exemptions explaining the family history and the children's medical history signed by a Dr. Christopher Scianna, who is licensed to practice in New York.
147. Dr. Scianna concluded that it was unsafe for either child to be vaccinated due to their current states of vulnerable health and their genetic analysis and family history of significant adverse vaccine reactions, including two deaths.
148. The exemption application also attached a letter from the genetic counselor.
149. The Lansing School District received the exemption letter and the children began school as usual in fall 2019.
150. On January 21, 2020, without warning, Jane Coe, Sr. received correspondence from Chris Pettogrosso, Superintendent of the Lansing School District, stating that "the building

principals” (Christine Rebera and Lorri Whiteman) had rejected the medical exemptions for both children. The family was given one week to get eleven different vaccines for each child to return to school.

151. The Superintendent noted that the school had received a recommendation from the NYSDOH and by unspecified members of a “medical team” locally but asserted that the building principals each ultimately made the decision to reject the medical exemptions “independently.”

152. Attached to the letter from the school was a letter dated December 5, 2019 written by Defendant Elizabeth Rausch-Phung, M.D., M.P.H., the Director of the Bureau of Immunizations at the New York State Department of Health.

153. Dr. Rausch-Phung stated that the adverse reactions of family members (including death) are not contraindications for immunization under ACIP and concluded that “there is not sufficient information included regarding the genetic testing performed to conclude that vaccines required for school attendance would be contraindicated in a child with variations in the reported SNPs. The specific source of the genetic tests, the results of these tests, and review and recommendations of this child’s genetic findings by a medical genetics specialist would be needed to determine if these results preclude this student from being vaccinated.”

154. Before rejecting the medical exemption, neither the school district nor Dr. Rausch-Phung contacted the family or Dr. Scianna seeking any further information or requesting to consult with the treating physician or geneticist.

155. On January 27, 2020, the family submitted a letter from an attorney and the genetic counselor explaining that the only pediatric genetic specialist in the region had a waiting list for new patients of more than one year.

156. The attorney requested that the school district meet to discuss the denial or grant the family a few months extension to try to expedite an appointment and satisfy Dr. Rausch-Phung's requirement that they provide a corroborating opinion written by a genetic specialist. She also expressed concern with the legality of the process, stating,

"I have serious concerns about the legality of this denial and process. Nothing in the law suggests that the family must retain the services of a specialist to be considered for an exemption. To the extent that the DOH isn't sure about a medical precaution, they should defer to the treating physician and the family. Moreover, there are constitutional issues here involving the fundamental rights of the family to refuse medical treatment especially where the treating physician and providers concur that it could be dangerous to the children's health. And particularly in a case like this, where the family has already had to suffer the death of more than one child due to vaccine reactions. To require such additional process is in my opinion unlawful and clear overreach."

157. On January 29, 2020, counsel for the Lansing School District emailed the Coe family attorney denying the requests for a meeting or an extension, and stating:

"finally, you cite your 'serious concerns' about the legality of the denial process" ...[relating to the NYSDOH recommendations]...However, this statement from a recommendation from the Department of Health was neither relied upon nor cited by the district in its decision to deny the medical exemption request." No indication was given about an alternative reason for the denial other than that the building principals had allegedly "made the decisions independently."

158. Though the medical exemption was permanently denied in January 2020, and there is no appeal pending, on May 4, 2020, the NYSDOH wrote Dr. Scianna seeking all of the children's medical records and noting that they were entitled to the full medical records of the children whether or not the family consented.

159. The intimidating letter from the NYSDOH vaguely references investigations and appears to have been sent to deter the physician from writing any further medical exemptions.

160. The children have been excluded from school since January 29, 2020. The burden on the family and children of trying to homeschool while the parents work has been very difficult and has caused the family significant economic and emotional damage.

John Foe

161. John Foe (“John”), age 11, was born with Hirschsprung’s Disease, a rare genetic disease which prevents connections between the brain and gastrointestinal system from forming.

162. As an infant, John had to undergo major gastrointestinal surgery during which surgeons removed a section of his intestine and then reattached the system back together. He must use a prosthetic colon system that needs to be inserted every night to keep him socially continent.

163. The surgery profoundly affected John’s immune system. More than 70% of the immune system is in the gastrointestinal system.

164. John suffers from a long list of severe allergies. He is so sensitive to chemicals and metals that he cannot wear sunscreen or even drink tap water. When John drinks water that is not filtered correctly, he has cramping, diarrhea, and bleeding rash around his rectum. He has experienced the same type of reaction to dairy, fruit, and most antibiotics, among other triggers. When antibiotics are necessary, John requires hospitalization to manage his adverse symptoms of vomiting, diarrhea and dehydration and requires concurrent administration of metronidazole to minimize reaction symptoms.

165. Another of John’s known triggers is immunization. John had a severe reaction to immunization at age 3.

166. John has not received any immunizations since the age of three on the advice of his pediatrician, Dr. Kari Bovenzi, M.D. (“Dr. Bovenzi”). Due to his serious reaction to immunization, and taking into consideration John’s medical history and his family medical history (John’s mother suffered paralysis after receiving the DTaP shot), John’s doctor determined that he was at substantial risk of having even more severe reactions to subsequent immunization and recommended that he should not receive any more.

167. On or about August 23, 2019, John's family submitted a properly certified medical exemption from Dr. Bovenzi, a physician licensed to practice medicine in New York, detailing why John should be exempt from further immunization requirements. John's parents spoke to the school nurses and were told that all their paperwork was in order.

168. On September 23, 2019, John's mother received a call from the Albany City School District Transportation Department letting her know that since John's medical exemption was denied, he would not be able to take the bus the next day. The family called the school, spoke to the principal, Michael Paolino, several school nurses and ultimately Assistant Superintendent Lori McKenna.

169. Ms. McKenna informed the family that John was no longer allowed to attend school and that the medical exemption was being denied on the advice of the district physician, Dr. Laura Staff.

170. John's family would not immunize their son against medical advice. The school district expelled John the same day. John has been unable to attend public school since September 23, 2019.

171. John is a very social child and loved school. He was beloved by his classmates. He was an honors student, an avid participant in marching band, chorus, chess club and running club, and affectionately referred to as the "mayor" of his school.

172. John also has special needs and qualified for and received critical services under a 504 plan at school.

173. Following his expulsion from school, the district refused to provide John with these services at home.

174. Expulsion from school had a significant adverse impact on John. John developed serious depression and was angry, confused and humiliated by his exclusion.

175. John's family hired an attorney and got extensive genetic testing for John. John carries the MTHFR gene mutation from his maternal side and has several other genetic vulnerabilities that reveal why immunization is particularly dangerous for him. John's pediatrician prepared a forty-page medical exemption, providing extensive detail about why John was at risk of harm from further immunization. The exemption was submitted shortly before Thanksgiving, 2019.

176. On January 3, 2020, the family received a letter from the school indicating that they'd sent the exemption letter "to the CDC" for review and had determined that it did not meet the criteria laid out in the ACIP guidelines and was therefore again denied. No detail was provided about who reviewed the letter specifically or what their specific recommendations were based on.

177. Despite their deep roots in the area, and that their careers were centered in New York, John's family began making plans to leave the state.

178. Before upending their lives and finding new careers, the family applied to private school in the same district. The first private school they sent the exemption accepted it right away. However, the tuition was too high for the family to handle. The second private school took a month to review the application and accepted it and John has been attending this private school since March 2020.

179. Though the family is relieved to have a school option for John, it is significantly impacting their lives and John's educational opportunities to be denied the right to a free public

education. At private school, John is not receiving the services that he would be able to receive in public school, and his family can ill afford to keep sending him there.

180. John wants to return to his public school, where he was so at home and beloved.

**Jane Goe**

181. Jane Goe (“Jane”) is a seventeen-year old young woman who suffers from multiple severe autoimmune conditions. Her diagnoses including Type I Diabetes, Celiac Disease, Hashimoto’s Thyroiditis, Alopecia Areata and Polycystic Ovarian Syndrome.

182. Jane lives with her parents, Jane Goe, Sr., and John Goe, in the Penfield Central School District.

183. Jane’s Type I Diabetes was triggered by the H1N1 vaccine in third grade. In rapid succession, she continued to devolve after that event and developed four additional autoimmune diagnoses, losing half of her hair, suffering chronic additional health issues, and missing significant time in school when she was too sick to attend.

184. Jane has a family history of serious autoimmune disease. Her genetic testing shows significant vulnerabilities including the rare HLA genotype, which places her at a high risk of developing Guillain-Barre syndrome (an acknowledged potential adverse reaction to the meningococcal vaccine). Jane is very sensitive to chemicals. She has had serious adverse reactions to chlorine and many other environmental exposures.

185. Since sixth grade, Jane and her family have worked extensively with Jane’s treating physician, Dr. Pamela Grover (“Dr. Grover”), who is licensed to practice medicine in New York and who has been so engaged for more than twenty years and is well-regarded for her expertise in autoimmune conditions.

186. Dr. Grover worked diligently with the family to help Jane regain and maintain a reasonable level of health. Jane avoids environmental triggers, must follow a restricted diet, and is undergoing multiple therapies. She has not received additional vaccines since her adverse reaction in third grade.

187. On or about August 18, 2019, Dr. Grover submitted a duly certified medical exemption from immunization, noting that Jane was suffering from a flare up of her acute autoimmune conditions and could not safely be immunized for at least one year or until her autoimmune conditions were under control.

188. Jane has had all her immunizations except for the meningococcal vaccine and a fifth dose of the tetanus, pertussis and diphtheria containing vaccine.

189. No component of any of these four vaccines protects anyone but the recipient.

190. On September 11, 2019, Mark Sansouci, the Assistant Superintendent of the Penfield Central School District, emailed Jane Goe, Sr. advising that the medical exemption for Jane was being denied on the advice of the School District's consulting doctor, Dr. Robert J. Tuite ("Dr. Tuite"). Dr. Tuite is a pediatrician, who does not have expertise in any of the autoimmune conditions from which Jane suffers.

191. Dr. Tuite's email, which was forwarded in the same thread, stated that the request was denied and that Jane would have had to have *suffered* Gullian-Barre Syndrome (which causes paralysis) within six weeks of getting a vaccine and that "it is up to the parents and/or physician to contact pediatric infectious disease/immunology or the DOH department of immunizations to get the specialist's input" for the exemption to be considered. Dr. Tuite noted that if Jane did not submit a letter from a specialist within fourteen days, she would be excluded from school.

192. With great difficulty, Jane's mother was able to get an appointment with Dr. Craig Orlowski ("Dr. Orlowski"), who has been practicing medicine for nearly forty years, serves as an Associate Professor of Clinical Pediatrics at the University of Rochester Medical School, is Chief of Pediatric Endocrinology the University of Rochester Golisano Children's Hospital, is a specialist and physician duly licensed in the state of New York and has published widely on many of the autoimmune conditions that Jane suffers from. Dr. Orlowski agreed that it would be unsafe for Jane to receive immunizations at that time and wrote a letter supporting an exemption through April of 2020.

193. Dr. Orlowski's exemption was submitted on or about September 18, 2019. Later that same day, Jane's mother received an email from Thomas Putnam, the Superintendent of the Penfield Central School District, forwarding another denial from Dr. Tuite, which stated:

*"Dr. Putnam, I have a lot of admiration for Dr. Orlowski as a pediatric endocrinologist but quite frankly feel that he is out of his scope of practice/expertise within this area of immunization issues. Believe me that I am so busy right now with these immunization concerns that it would be really easy to just accept this medical exemption and move on. I still feel strongly that this request does not meet the CDC contraindication or even a precaution from getting these specific vaccines. I would highly recommend a referral to either a pediatric infectious disease/immunology specialist such as Dr. Geoffrey Weinberg at Golisano Children's Hospital or an immunologist such as Dr. Syed Mustafa...who both have a wealth of experience and expertise in this area of immunization appropriateness. I have in the past and would now honor and trust their opinion and abide by their advice in these kind of complicated situations."*

194. Dr. Tuite is a pediatrician specializing in sports medicine. He has no specialized training or certifications in vaccines or in any of the conditions that Jane suffers from and has nowhere near the level of expertise in these matters that Dr. Orlowski does.

195. The next day, Jane was removed from school as the fourteen days from the original notice of denial had run. It was homecoming that day. The exclusion was public. Many people at school were aware of the reason and mentioned that they knew that she was excluded because her medical exemption had been denied. Jane was humiliated and felt that her privacy had been seriously violated.

196. Jane's mother showed Dr. Tuite's email to Dr. Orlowski, who was so outraged that he walked across the hall and presented it to his colleague Dr. Geoffrey Weinberg ("Dr. Weinberg"), one of the two doctors that Dr. Tuite suggested were the only specialists that he would consider fit to submit a medical exemption application.

197. On or about September 20, 2020, Dr. Weinberg submitted a letter to Dr. Tuite affirming the validity of his colleague Dr. Orlowski's medical exemption request and recommending that Dr. Tuite accept the medical exemption for Jane at least through the fall given that she was having a flare of symptoms and was at risk of exacerbating her condition.

198. Jane was allowed to attend her senior year of high school through the fall, but Dr. Tuite indicated that she would need to be immunized by January 28, 2020 or she would be removed from school.

199. The family had to hire an attorney. The fall semester was bittersweet for Jane, who suffered enormous stress at the idea that she would be removed from school in the spring semester. Jane had been chosen to play a significant part in the spring play and was terrified that she would not be able to graduate with her classmates or have to suffer another humiliating removal from school and all the gossip and judgment that followed the first one.

200. In January 2020, Jane's family submitted a follow up medical exemption request, written by Dr. Grover, which documented how the request fit into the ACIP guidelines.

201. The request was sent on to the Department of Health for further review.

202. Since this submission, Jane has not heard back, either with an acceptance or denial. The stress on the family of wondering if Jane would be removed from school at any moment has been enormous. Jane is set to graduate on July 30, 2020. Her speech has been chosen as the commencement speech. Though this graduation is only a day away, Jane is terrified that just by joining this lawsuit she might be subjected to retaliation and denied the right to graduate with her class.

203. The financial and emotional burdens placed on Jane and her family this year have irreparably impacted her emotional and physical health and her family's wellbeing.

**John Joe**

204. John Joe ("John") is a six-year-old boy who had a severe, life-threatening anaphylactic reaction to his hepatitis B vaccine given at birth. He lives with his mother, Jane Joe, who is a single mother without financial resources or support residing with her son in the Ithaca City School District.

205. John has special needs. He has severe autism, obsessive compulsive disorder, and a range of neurological and other health problems. Medical tests show mercury poisoning, lead poisoning and aluminum poisoning and an inability to process heavy metals. Jane has worked extensively with medical professionals and with rigorous dietary and environmental protocols, which have greatly improved her son's quality of life and health over the years. Nonetheless, his health is fragile, and setbacks are common.

206. On the advice of his treating physicians, John has had a medical exemption to all immunization since the anaphylactic reaction at birth.

207. In 2018, John and Jane moved to the Ithaca City School District. John's treating pediatrician in Ithaca, Dr. Jessica Casey, a physician licensed to practice medicine in New York, reviewed John's case and wrote a medical exemption for John, indicating her recommendation that he be exempt from all immunizations on a permanent basis.

208. Jane submitted Dr. Casey's medical exemption to the Ithaca City School District in the fall of 2018, and John completed that school year without issue.

209. In the summer 2019, Jane obtained a renewed medical exemption from Dr. Casey and submitted it again without issue. John attended his summer programming for children with special needs and began his first-grade year in elementary school in the fall.

210. In November, 2019, without warning, the Superintendent of the Ithaca City School District, Dr. Luvelle Brown, signed a letter to Jane letting her know that her medical exemption request was partially denied, and she had to get her son immunized within a week or her son would be expelled from school.

211. Jane met with Dr. Brown to beg him to reconsider, explaining that her son had always had a medical exemption to all further immunization and that multiple physicians had indicated that further immunization would be unsafe for him.

212. Dr. Brown, who is not a medical professional or scientist, stated that it was out of his hands, and that as far as he understood, John would need to have an anaphylactic reaction to each vaccine in order to be exempt from the additional mandates.

213. John was removed from school in November of 2019. His mother has had to quit her job, go on public assistance, and now attempts to attend to all her son's needs on her own.

214. Before he was removed from school, John had an Individualized Educational Plan, which entitled him to extensive needed services, such as speech therapy five days a week,

occupational therapy three times a week, music therapy and play therapy. The Ithaca City School District has refused to provide any of these services at home as they do for other special needs children who are homeschooling.

**Jane Koe, John Koe and Janie Koe**

215. Jane Koe (age 14), John Koe (age 11) and Janie Koe (age 5) live with their parents, Jane Koe, Sr. and John Koe, Sr. in the Shenendehowa Central School District in New York. Jane Koe and John Koe both suffer from serious autoimmune and other chronic health issues believed to have been triggered by their childhood immunizations.

216. Jane received her normal schedule of vaccines until she suffered a severe reaction to her one-year immunizations just before her first birthday. Pain and hardness at the injection site led to uncontrollable high fever which would not subside for over a week. Within days, Jane lost her ability to walk. She spent her first birthday in the hospital and ended up having to undergo extensive medical treatment including surgery.

217. At age three, Jane developed migraines so severe that she was repeatedly in and out of the emergency room throughout childhood and has missed substantial school, spending a number of years on homebound instruction due to her illness. Jane suffers from crippling arthritis, serious heart issues, numbness that leads to an inability to breathe and frequent autoimmune conditions. Jane's bloodwork reveals markers indicating Sjogrens Syndrome and/or Lupus, both inflammatory autoimmune conditions which immunizations can trigger and make worse.

218. John received his hepatitis B shot the day he was born. He immediately developed eczema and serious ongoing gastrointestinal issues along with neurological tics. Like his sister, John has had to spend substantial time out of school and in the ER due to his health issues and had to be educated through home instruction due to illness.

219. In or around 2014, John's gastrointestinal issues became so bad that he had uncontrollable explosive diarrhea for over a year. For several years, the family was in and out of the emergency room for one child or the other every few weeks.

220. In 2018, John was diagnosed with two forms of juvenile autoimmune arthritis and his family was informed that he will likely end up in a wheelchair. Juvenile autoimmune arthritis is a recognized adverse reaction to immunization.

221. John's cousin has the same condition. He was treated with chemotherapy drugs and ended up having liver failure as a child.

222. The family history reveals significant vulnerability for autoimmune disease and cancers as well as adverse vaccine reactions.

223. Janey Koe, the only one of the three children who has never been vaccinated, has no health issues.<sup>10</sup> Jane Koe, Sr. has been able to mitigate some of the symptoms of her older children's autoimmune conditions through rigorous diet modifications (the children have to stay on a gluten free and vegan diet) and the avoidance of known triggers, including immunization.

224. The children are under the care of a nurse practitioner, Melanie Clark, R.N./N.P. who is familiar with the children's treatment and has documented an improvement in the children's health as a result of the diet and lifestyle adjustments the family has made.

225. N.P. Clark agrees that immunization could harm the children and, before the start of school in 2019, wrote a letter seeking medical exemption for each of the three children.

226. The Superintendent of the Shenendehowa Central School District rejected the exemptions, stating that they had to be signed by a medical doctor. The doctors in the practice refused to sign the forms and refused to even evaluate the children despite the treating nurse practitioner's

assessment. As a result, the School District advised Jane Doe that her children had to withdraw from school.

227. The District asked Jane Doe, Sr. to sign forms indicating that she was voluntarily removing her children from school.

228. Jane Doe, Sr. objected, responding that her children were being involuntarily expelled and explaining that she was providing her children with home school education under duress and unwilling to sign forms stating this was voluntary.

229. The Shenendehowa Central School District retaliated by filing a child abuse and neglect complaint against Jane Doe, Sr. with Child Protective Services (“CPS”) hotline, causing the family to endure an invasive CPS investigation. No formal report was issued, but as a result, the family now feels vulnerable and “in the system.”

**John Loe**

230. John Loe (“John”) is a fifteen-year-old boy diagnosed at around age 7 by pediatric neurologist Rosario Trifiletti, M.D., Ph.D. (“Dr. Trifeletti”) with two forms of autoimmune encephalitis: Pediatric Acute-Onset Neuropsychiatric Syndrome (“P.A.N.S.”) and later (August 2013) with a dual diagnosis of Hashimoto’s Encephalopathy.

231. John lives with his parents, Jane Loe and John Loe, Sr., and attends a Catholic college preparatory school in the neighboring South Huntington School District.

232. Since his first day of life and for the next several years, John was vaccinated in strict accordance with pediatric directives, apparently pursuant to New York State mandates based on ACIP guidelines, plus all of the influenza (“flu”) and H1N1 flu vaccines strongly recommended. Through the years, John suffered unexplained “phases” of odd behavioral and

health issues. Later review of the medical file revealed that these phases closely tracked his immunizations.

233. At age 5, on or about October 9, 2009, John was vaccinated with the DTaP and flu shots, and then received two H1N1 vaccines over the course of the next weeks. Following the 2009 vaccines, John appeared to decompensate more sharply than prior “phases” his parents had noticed in previous years.

234. At age 6, on October 27, 2010, John received a flu vaccine, and the above referenced symptoms heightened further still, to a more severe degree than his parents had ever seen. Teachers noticed that something was wrong, but John’s health seemed to improve over the course of the year.

235. At age 7, on October 18, 2011, John had another flu vaccine at his pediatrician’s behest. Over these next days, weeks and months John’s health drastically deteriorated. He began to experience debilitating tics and compulsions, which would occur simultaneously, appearing intertwined and a terrible waterfall of symptoms and behaviors. He repeatedly clapped his hands so hard next to his ear that he was later diagnosed with self-inflicted hearing damage, had terrifying panic attacks in public, banged his head and suffered extreme general anxiety, extreme separation anxiety, and extreme school anxiety. He developed obsessive-compulsive disorder, and suffered loss of penmanship, math, reading and writing skills and toileting skills.

236. Things worsened still when he became nearly anorexic, refusing more and more foods until he was down to a sip of water and a bite of saltine cracker a day. He began having quasi-hallucinations, experiencing intense fear to a debilitating degree. He grew increasingly sad, which apparently evolved into grave depression, as he said, “I want to kill my life.”

237. At this point, his bewildered parents grew from wondering what was happening to their child to being terrified beyond words. In 2012, the parents got an appointment with Dr. Trifiletti, who is a well-respected pediatric neurologist.

238. Dr. Trifiletti diagnosed John with P.A.N.S./P.A.N.D.A.S. a form of autoimmune encephalopathy, which was confirmed upon his analysis of comprehensive bloodwork reports. The parents complied with the recommended immune modulating treatments of Dr. Trifiletti. Within 24 to 48 hours, John began eating again, his hallucinations stopped, and slowly over time, many other symptoms improved.

239. Dr. Trifiletti was able to stabilize John's neurological and autoimmune condition slowly with the medications, ongoing monitoring and testing, and avoidance of known triggers, such as exposure allergens, toxins, and vaccines.

240. Under Dr. Trifiletti management of John's condition he fared relatively well, compared to many with his diagnoses. Though John never made it back to "baseline" symptoms-wise, and though he still suffers setbacks, he has remained highly functional.

241. In August 2012, when Dr. Trifiletti began treating John, he was not due for any further school-mandated vaccinations, already being fully "up to date."

242. When John reached 6<sup>th</sup> grade (fall 2015), the school nurse advised that the Tdap was required to remain in school. Dr. Trifiletti, advised that a medical exemption was medically indicated for John as to "all vaccines". The exemption was accepted without issue. John's family submitted subsequent medical exemptions from Dr. Trifiletti for 7<sup>th</sup>, 8<sup>th</sup>, and 9<sup>th</sup> grade, also without issue.

243. In August 2019 Dr. Trifiletti signed an updated medical exemption, which the parents submitted to John's school in mid-September 2019.

244. Shortly thereafter, the school nurse contacted the parents to advise that their school's "chief doctor," Dr. Jack Geffken ("Dr. Geffken") rejected Dr. Trifiletti's exemption after speaking with him on the phone.

245. After this phone call, Dr. Trifiletti, who had been treating John since he was seven years old, told John's parents that he could no longer treat John. He behaved oddly and as if he was frightened. Months after dropping John as a patient, Dr. Trifiletti followed up with a stiff letter that made no sense, given that John was no longer a patient, indicating the benefits of vaccines and contradicting years of documented medical advice about the risks that they pose to John specifically.

246. John was removed from school on September 20, 2019 and has not been able to return since.

247. For the remainder of fall 2019, the family's life revolved around the uphill battle of trying to get John back into school and to find a new specialist. There are few specialists with expertise sufficient to treat John's conditions and the waiting lists are long for all of them. John's health and academics declined dramatically.

248. In November 2019, the Loes obtained an appointment with specialist, Dr. Denis Bouboulis, an immunologist licensed to practice in New York, who is experienced and revered in the PANS/Autoimmune Encephalitis community.

249. Dr. Bouboulis concurred that it would be unsafe for John to receive the Tdap or meningococcal vaccines. Accordingly, on or about November 14, 2019, he provided two written medical exemptions (the school adamantly insisted there had to be a separate form for each vaccine in question, which misstates the requirement of setting forth the bases as to each vaccine).

250. Months of bureaucratic delay ensued.

251. First, the school advised that the district doctor, Dr. Geffken, declined the Medical Exemptions because it was on the “wrong form.” Dr. Bouboulis’s office had utilized the current New York City DOH forms, believing that to be the most currently required New York form, and the parents were unable to suggest otherwise, as they were neither present while it was completed, nor aware of more than one form version (NYC vs. State). The NYC form is *more comprehensive* than the New York State form and includes all the same information as the state form.

252. John’s parents pleaded for more time to have the doctor redo the forms on the New York State form, which was begrudgingly granted. They then undertook ongoing and diligent efforts to arrange for the doctor to transfer the information to the New York State forms, but had difficulty getting a response. They eventually were told by staff that during that time, Dr. Bouboulis had received a call from the NYSDOH, directing that he could not write any further New York medical exemptions “unless he was the doctor who administered the vaccinations,” and that therefore, he would not be signing any more. Nothing in the law or regulations supports this limitation on physicians.

253. At their next medical appointment with Dr. Bouboulis, in early December 2019, Dr. Bouboulis reiterated what the staff had said. The Loe’s showed Dr. Bouboulis legal analysis from counsel and the text of the statute contradicting the NYSDOH erroneous information. To the extent that Dr. Bouboulis was merely transferring information from the NYC forms to the New York State forms as requested by the school, and not issuing anything anew (post-handling), he agreed to prepare the new forms. These comprised what was now *the third* medical exemption submission to the school since the school year began.

254. On January 7, 2020, the parents received an email from the principal stating that due to information contained in an attached letter recommending a denial of the exemption from Dr. Geffken, John would be unable to continue as a student there. The principal had advised all of John's teachers and departments, including the Registrar, of the reason, and that he would keep the family in his prayers.

255. John has all his immunizations except for a final booster dose of the Tdap vaccine (tetanus, diphtheria, and pertussis) and the meningococcal vaccine (meningitis).

256. No component of any of these four vaccines protects anyone but the recipient.

257. The impact of John's school expulsion upon his family and him has been severe.

258. John's medical condition has made his life unbearable at times. A hallmark of his condition is severe social anxiety. John was just at a point of recovering enough health to begin to develop confidence. He was doing well in school. He was getting recognition for his music and was excited to be in several school bands. He was finally overcoming some of his social anxiety and making friends.

259. John's confidence and the progress he's made have also been shattered. He has become very depressed and is not able to keep up with his home studies.

260. John's college prospects and the course of his life have been substantially altered for the worse. His parents work full time and home instruction has not been successful. Additionally, John was forced to miss the P.S.A.T. preparation and test that 10<sup>th</sup> graders take at school.

261. John feels hopelessly lost and his depression and anxiety have become debilitating. His mother has been in touch with a few psychologists who can provide counseling about his situation, feelings, and homeschooling encouragement, but John refuses to engage and has shut down to an alarming degree.

**MEDICALLY FRAGILE CHILDREN ACROSS THE STATE ARE BEING SUBJECTED TO SIMILAR BURDENS AND TREATMENT**

262. The stories of the named plaintiffs illustrate a wider pattern and practice that arbitrarily excludes most medically fragile children from obtaining medical exemptions in New York.

263. They provide typical detail about how the new regulations narrowing New York's medical exemption from mandatory school immunization, and the policies, procedures and practices adopted by the defendants in implementing them are too restrictive. Instead of helping medically fragile children, these practices are subjecting medically fragile children and their families to extensive harm, including the threat of unsafe medical interventions, enormous stress, and severe financial burdens.

264. The ACIP contraindications and precautions are not comprehensive and were never meant to be an exhaustive list of reasons for a physician to determine that one or more of the vaccines are dangerous for a child.

265. Dr. Andrew Kroger from CDC's Immunization Services Division emphasized this point in reply to an email from Plaintiff Jane Doe asking for clarification on the ACIP guidelines and their role in defining medical exemptions. He stated: "*The ACIP guidelines were never meant to be a population-based concept...The CDC does not determine medical exemptions. We define contraindications. It is the medical providers prerogative to determine whether this list of conditions can be broader to define medical exemptions.*" Email from Dr. Kroger to Jane Doe sent December 28, 2019.

266. The ACIP contraindications only allow "contraindicate" immunization for four narrow circumstances:

- a. The child suffered near fatal anaphylactic shock or a coma within a short period after receiving a vaccine (which only qualifies the child for an exemption from the

triggering vaccine(s) and requires that a child continue to submit to the other vaccines until or unless he has suffered near fatal anaphylactic shock to each one shortly after it's administration);

- b. The child has a narrow category of severe immunodeficiency (certain pediatric cancers but only during active chemotherapy, HIV, organ transplant) (which only qualifies the child for exemption from certain live vaccines);
- c. The child developed encephalopathy within seven days after immunization with diphtheria, tetanus and pertussis containing vaccines (which only qualifies the child for further exemption from those specific vaccines); and
- d. The child developed intussusception after rotavirus vaccine (which only qualifies the child for an exemption from further rotavirus vaccine).

267. The ACIP precautions expand the category of children who should be exempt. However, the precautions are vague, complex and are subject to interpretation which often results in inconsistent results.

268. Moreover, many consulting physicians including Dr. Rausch-Phung from the NYSDOH appear to be judging medical exemption requests solely on whether they comport with ACIP contraindications, ignoring conditions that fall under precautions entirely.

269. Even if the precautions were honored, the ACIP guidelines are too narrow. Hundreds of additional adverse reactions have been recognized even by the vaccine manufacturers themselves, and hundreds of additional well-established medical reasons may cause a child to be at risk of harm from one or more of the childhood immunizations.

***ACIP Doesn't Cover Most Harms Recognized in Vaccine Package Inserts***

270. The ACIP contraindications do not even cover most of the harms recognized and published in the vaccine package inserts by the vaccine manufacturers.

271. After licensure, the law requires vaccine manufacturers to include in the package insert for their product “only those adverse events for which there is some basis to believe there is a causal relationship between the drug and occurrence of the adverse event.” 21 C.F.R. 201.57(c)(7).

272. The following list, meticulously compiled by Plaintiff Children’s Health Defense, highlights the “contraindicated” ACIP list among all listed vaccine adverse reactions and conditions in marketed vaccines:

## **Vaccine Package Inserts: Post-Marketing Experience**

### **Blood and lymphatic system disorders**

- **Anemia, aplastic or hemolytic** (Pneumovax-23, ProQuad, Varivax)
- **Autoimmune hemolytic anemia** (Gardasil/Gardasil 9)
- **Epistaxis [nosebleed]** (ProQuad)
- **Extravasation blood** (ProQuad)
- **Hematochezia [bloody stools]** (ProQuad, Rotarix, RotaTeq)
- **Increased erythrocyte sedimentation rate** (Recombivax)
- **Leukocytosis** (MMR-II, Pneumovax-23)
- **Lymphadenitis** (Boostrix, Pneumovax-23, ProQuad)
- **Lymphadenopathy, including regional [enlarged lymph nodes]** (Boostrix, Daptacel, DT, Fluad, Fluarix, Flulaval, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, Infanrix, IPV, Kinrix, MMR-II, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, Tenivac)
- **Thrombocytopenia, including severe [low platelets]** (Afluria, Engerix-B, Fluad, FluzoneQ and FluzoneHD, Havrix, Infanrix, Kinrix, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix, Vaqta, Varivax)
- **Thrombocytopenic purpura, idiopathic (ITP)** (Gardasil/Gardasil 9, Rotarix, Twinrix, Varivax)

#### **Cardiac disorders**

- **Cyanosis [bluish discoloration]** (Daptacel, Hiberix, Infanrix, Pediarix, Pentacel, Prevnar-13, Quadracel)
- **Myocarditis [inflammation of heart muscle]** (Adacel, Boostrix)
- **Palpitations** (Engerix-B, Twinrix)
- **Pericarditis [inflammation of pericardium]** (FluMist)
- **Tachycardia [abnormally high heart rate]** (Engerix-B, Fluarix, Recombivax, Twinrix)

#### **Congenital**

- **Congenital anomaly** (Havrix)

#### Death

- **Death** (Gardasil/Gardasil 9, MMR-II, Rotarix, RotaTeq)
- **SIDS** (Infanrix)

#### Ear and labyrinth disorders

- **Ear pain** (Engerix-B, Infanrix, ProQuad, Twinrix)
- **Nerve deafness** (MMR-II, ProQuad)
- **Otitis media** (MMR-II)
- **Tinnitus** (Engerix-B, Recombivax, Twinrix)
- **Vertigo** (Engerix-B, Fluarix)

#### Eye disorders

- **Conjunctivitis** (Engerix-B, Fluarix, MMR-II, Recombivax, Twinrix)
- **Eye irritation** (Fluarix, ProQuad)
- **Eye pain** (Fluarix, Flulaval)
- **Eye redness** (Fluarix)
- **Eye swelling** (Bexero, Fluarix)
- **Eyelid swelling** (Fluarix, ProQuad)
- **Keratitis** [*cornea inflammation*] (Engerix-B)
- **Ocular hyperemia** [*eye inflammation*] (FluzoneQ and FluzoneHD)
- **Ocular palsies** (MMR-II, ProQuad)
- **Optic neuritis/neuropathy, papillitis** (Engerix-B, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Twinrix)
- **Photophobia** (Flulaval)
- **Retinitis, necrotizing retinitis** (MMR-II, ProQuad, Varivax)
- **Retrobulbar neuritis** (MMR-II, ProQuad)
- **Uveitis** [*eye inflammation*] (Recombivax)
- **Visual disturbances** (Engerix-B, Recombivax, Twinrix)

#### Gastrointestinal disorders

- **Abdominal pain or discomfort** (Fluarix, ProQuad)
- **Candidiasis** (ProQuad)
- **Constipation** (Recombivax)
- **Diarrhea** (Daptacel, FluMist, FluzoneHD, MMR-II, Pediarix, Pentacel)
- **Dyspepsia** (Engerix-B, Twinrix)
- **Dysphagia** [*swallowing difficulties*] (Flulaval)
- **Gastroenteritis** (Rotarix, RotaTeq)
- **Intussusception and recurrent intussusception (including fatal)** (Rotarix, RotaTeq) (*(ACIP would allow exemption from further immunization with rotavirus vaccine only)*)
- **Mouth ulcers** (ProQuad)
- **Nausea** (Daptacel, DT, Fluarix, FluMist, FluzoneHD, Gardasil/Gardasil 9, MMR-II, Pneumovax-23, TDVAX)
- **Pancreatitis** (Gardasil/Gardasil 9, MMR-II)

- **Swelling of the mouth, throat, and/or tongue (Fluarix)**
- **Vomiting (Flulaval, FluMist, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, MMR-II, Pediarix, Pentacel, Pneumovax-23, Tenivac)**

#### General disorders and administration site conditions

- **Abnormal gait (Flulaval)**
- **Apathy (ProQuad)**
- **Asthenia [fatigue, weakness] (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, Infanrix, Pediarix, Tenivac)**
- **Body aches (Fluarix)**
- **Chest pain (Fluarix, Flulaval, FluzoneQ and FluzoneHD)**
- **Chills (Fluarix, FluzoneHD, Gardasil/Gardasil 9)**
- **Decreased limb mobility (Pneumovax-23)**
- **Feeling hot (Fluarix)**
- **Fever (MMR-II, Pneumovax-23)**
- **Injected limb—extensive swelling (ActHIB, Bexero, Hiberix)**
- **Injection site abscess (Adacel, Daptacel, Fluarix, Flulaval, PedvaxHIB, Pentacel, Quadracel)**
- **Injection site bruising (Adacel, Flulaval)**
- **Injection site cellulitis (Afluria, Daptacel, Fluad, Fluarix, Flulaval, Pediarix, Quadracel, Tenivac)**
- **Injection site reactions: mass, pain, warmth (Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, Havrix, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, TDVAX, Tenivac, Twinrix)**
- **Injection site rash (Daptacel, Flulaval, IPV, Prevnar-13)**
- **Listlessness (Quadracel)**
- **Malaise (Gardasil/Gardasil 9, MMR-II, Pneumovax-23, TDVAX, Twinrix)**
- **Peripheral edema (ActHIB, MMR-II, Pneumovax-23, ProQuad, TDVAX, Tenivac, Varivax)**
- **Pyrexia (TDVAX)**
- **Swelling (MMR-II, ProQuad)**

#### Hepatobiliary and liver disorders

- **Elevation of liver enzymes (Recombivax)**
- **Hepatitis (Havrix, Twinrix)**
- **Jaundice (Havrix, Twinrix)**

#### Immune system disorders

- **Allergic reactions/hypersensitivity (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluarix, Flublok, FluMist, FluzoneQ and FluzoneHD, Hiberix, Infanrix, IPV, Kinrix, Pediarix, Pentacel, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix)**
- **Anaphylactic and anaphylactoid reactions, including shock (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluad, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, RotaTeq, Tenivac, Trumenba, Twinrix, Varivax) (ACIP would only allow exemption from the triggering immunization only)**
- **Angioedema, angioneurotic edema [swelling beneath skin] (ActHIB, Adacel, Boostrix, Daptacel, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, Kinrix, MMR-II, Pediarix, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, RotaTeq, Tenivac, Twinrix, Varivax)**
- **Edema (Adacel)**
- **Hypotension (Adacel)**
- **Serum sickness (Afluria, Engerix-B, Fluarix, Havrix, Pneumovax-23, Recombivax, Twinrix)**

### Infections and infestations

- **Atypical measles (MMR-II, ProQuad)**
- **Bronchitis (Infanrix, ProQuad)**
- **Cellulitis (Daptacel, Infanrix, Pneumovax-23, ProQuad, TDVAX, Varivax)**
- **Chills (Havrix, Twinrix)**
- **Early-onset Hib disease (PedvaxHIB)**
- **Herpes simplex (ProQuad)**
- **Herpes zoster (Engerix-B, ProQuad, Recombivax, Twinrix, Varivax)**
- **Infection (ProQuad)**
- **Influenza, influenza-like illness (Afluria, Flulaval, Havrix, ProQuad)**
- **Invasive Hib disease (Pentacel)**
- **Kawasaki disease (Rotarix, RotaTeq)**
- **Laryngitis (Flulaval)**
- **Measles (ProQuad)**
- **Measles-like rash (MMR-II)**
- **Meningitis, aseptic meningitis, eosinophilic meningitis (Engerix-B, FluMist, MMR-II, Pentacel, ProQuad, Twinrix, Varivax)**
- **Pharyngitis (Fluarix, FluzoneHD, Varivax)**
- **Pneumonia, pneumonitis (MMR-II, ProQuad, Varivax)**
- **Pulmonary congestion (ProQuad)**
- **Respiratory tract infection (Infanrix, Pediarix, ProQuad)**
- **Rhinitis (Fluarix, Flulaval, FluzoneHD, Havrix, MMR-II, Pentacel, ProQuad)**
- **Secondary bacterial infections of skin and soft tissue (Varivax)**
- **Sinusitis (ProQuad)**
- **Skin infection (ProQuad)**
- **Sore throat (MMR-II, ProQuad)**
- **Tonsillitis (Fluarix)**
- **Transmission of vaccine virus strains to non-vaccinated (RotaTeq)**
- **Varicella (vaccine strain) (ProQuad, Varivax)**
- **Varicella-like rash (ProQuad)**
- **Viral infection (Pentacel)**

### Investigations

- **Abnormal liver function tests (Engerix-B, Twinrix)**
- **Increased serum C-reactive protein (Pneumovax-23)**

### Metabolic disorders

- **Decreased appetite (Pentacel)**
- **Diabetes mellitus (MMR-II)**
- **Mitochondrial encephalomyopathy/Leigh syndrome exacerbation [*neurometabolic disorder*] (FluMist)**

### Musculoskeletal and connective tissue disorders

- **Arthralgia (Boostrix, Engerix-B, FluzoneHD, IPV, MMR-II, Pneumovax-23, ProQuad, Recombivax, TDVAX, Twinrix)**
- **Arthritis (Engerix-B, Flulaval, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix)**
- **Back pain (Boostrix)**

- **Hypotonia** (Prevnar-13)
- **Lupus-like syndrome** (Recombivax)
- **Muscle spasm** (Adacel)
- **Muscle weakness** (Engerix-B, Fluad, Flulaval, Recombivax, Twinrix)
- **Musculoskeletal pain** (ProQuad)
- **Musculoskeletal stiffness** (Havrix)
- **Myalgia** (Boostrix, IPV, MMR-II, ProQuad, TDVAX, Tenivac)
- **Myositis** (Adacel)
- **Pain in extremities** (Fluarix, FluzoneQ and FluzoneHD, Pediarix, Recombivax, TDVAX, Tenivac)
- **Systemic lupus erythematosus (SLE)** (Recombivax)

#### Nervous system disorders

- **Acute disseminated encephalomyelitis (ADEM)** (MMR-II, ProQuad)
- **Ataxia** (MMR-II, ProQuad, Varivax)
- **Bulging fontanelle** (Pediarix)
- **Cerebellar ataxia** (Vaqta)
- **Convulsions/seizures** (ActHIB, Adacel, Afluria, Boostrix, Daptacel, DT, Fluad, Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, Hiberix, IPV, Kinrix, MMR-II, Quadracel, Recombivax, TDVAX, Twinrix, Varivax)
- **Depressed level of consciousness** (Boostrix, Pediarix, Pentacel)
- **Dizziness** (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, MMR-II, ProQuad, TDVAX, Tenivac, Varivax)
- **Encephalitis, vaccine-induced encephalitis [brain inflammation]** (Boostrix, Engerix-B, FluMist, MMR-II, Pediarix, Recombivax, Twinrix, Vaqta, Varivax) (*ACIP will only allow exemption from further vaccination with the triggering vaccine*)
- **Encephalomyelitis [inflammation of brain and spinal cord]** (Afluria, Fluad, Fluarix, FluzoneQ and FluzoneHD)
- **Encephalopathy [brain disease]** (Afluria, Engerix-B, Flulaval, Havrix, Infanrix, MMR-II, ProQuad, Twinrix)
- **Facial palsy, Bell's palsy** (Adacel, Boostrix, Engerix-B, Fluarix, FluMist, FluzoneQ and FluzoneHD, ProQuad, Recombivax, Twinrix, Varivax)
- **Facial (or cranial) nerve paralysis** (Flulaval)
- **Facial paresis [impaired movement]** (Fluarix)
- **Febrile convulsions/seizures** (Afluria, Daptacel, FluzoneQ and FluzoneHD, IPV, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Quadracel, Recombivax)
- **Guillain-Barré syndrome** (Adacel, Afluria, Engerix-B, Fluad, Fluarix, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Recombivax, Tenivac, Vaqta, Varivax)
- **Headache** (DT, Infanrix, IPV, MMR-II, ProQuad, TDVAX, Twinrix)
- **Hypoesthesia [decreased tactile sensitivity]** (Adacel, Engerix-B, Fluarix, Flulaval, Havrix, Recombivax, Twinrix)
- **Hypokinesia [loss of muscle movement]** (Flulaval)
- **Hypotonia [low muscle tone]** (Daptacel, Hiberix, Infanrix, Pediarix, Quadracel)
- **Hypotonic-hyporesponsive episode to immunization (HHE)** (Daptacel, Hiberix, Kinrix, Pediarix, Pentacel, Quadracel)
- **Lethargy** (Pediarix)
- **Limb paralysis** (Flulaval)
- **Measles inclusion body encephalitis (MIBE)** (MMR-II, ProQuad)
- **Migraine** (Engerix-B, Recombivax)
- **Multiple sclerosis (or MS exacerbation)** (Engerix-B, Havrix, Recombivax, Twinrix)
- **Myelitis [spinal cord disease]** (Adacel, Fluarix, FluzoneQ and FluzoneHD, Havrix, Recombivax, Twinrix)
- **Neuralgia [nerve pain]** (Afluria, Fluad)

- **Neuritis, including brachial, polyneuritis** [*nerve inflammation*] (Adacel, Afluria, Engerix-B, Fluad, Fluarix, FluzoneQ and FluzoneHD, MMR-II, Twinrix)
- **Neuropathy, polyneuropathy** [*nerve damage*] (Afluria, Engerix-B, Fluarix, Havrix, MMR-II, ProQuad, Recombivax, Twinrix)
- **Paralysis** (Engerix-B, Twinrix)
- **Paresis** (Engerix-B, Twinrix)
- **Paresthesia** [*abnormal skin sensations*] (Adacel, Afluria, Boostrix, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Havrix, IPV, MMR-II, Pneumovax-23, ProQuad, Tenivac, Varivax)
- **Partial seizures, seizures** (Daptacel, Engerix-B, ProQuad)
- **Presyncope** [*feeling faint*] (Fluad, Flucelvax)
- **Radiculopathy** [*"pinched nerve" in spine*] (Pneumovax-23, Recombivax)
- **Somnolence** (Daptacel, DT, Flulaval, Havrix, Hiberix, IPV, Pediarix, Pentacel, Quadracel, Recombivax)
- **Subacute sclerosing panencephalitis (SSPE)** (MMR-II, ProQuad)
- **Syncope, vasovagal syncope** [*fainting*] (Adacel, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, Kinrix, MMR-II, Pediarix, ProQuad, Recombivax, Tenivac, Trumenba)
- **Transverse myelitis** [*spinal cord demyelination*] (Afluria, Engerix-B, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Twinrix, Varivax)
- **Tremors** (Flulaval, ProQuad)

#### Psychiatric disorders

- **Agitation** (IPV, ProQuad, Recombivax)
- **Crying/unusual crying** (Pediarix)
- **Hypersomnia** (ProQuad)
- **Insomnia** (Flulaval, Pediarix)
- **Irritability** (MMR-II, Recombivax)
- **Nervousness** (Pediarix, ProQuad)
- **Restlessness** (Pediarix)
- **Screaming** (Daptacel, Pediarix, Pentacel, Quadracel)

#### Respiratory, thoracic, and mediastinal disorders

- **Apnea** (Engerix-B, Hiberix, Infanrix, Kinrix, Pediarix, Pentacel, Prevnar-13)
- **Asthma, asthma-like symptoms** (Engerix-B, Fluarix, Twinrix)
- **Bronchospasm** (Engerix-B, Fluarix, Flulaval, MMR-II, ProQuad, Recombivax, Tenivac, Twinrix)
- **Cough** (Fluarix, FluzoneQ and FluzoneHD, Infanrix, MMR-II, Pediarix, Pentacel)
- **Dyspnea** [*shortness of breath*] (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, Pediarix, Quadracel, Twinrix)
- **Dysphonia** [*vocal abnormalities*] (Flulaval)
- **Epistaxis** [*nosebleed*] (FluMist)
- **Oropharyngeal pain** (FluzoneQ)
- **Respiratory distress** (Fluarix)
- **Rhinorrhea** [*runny nose*] (FluzoneQ)
- **Stridor** [*high-pitched wheezing*] (Fluarix)
- **Throat tightness** (Flulaval, FluzoneQ and FluzoneHD)
- **Wheezing** (FluzoneQ and FluzoneHD, ProQuad)

#### Skin and subcutaneous tissue disorders

- **Acute hemorrhagic edema of infancy** (MMR-II, ProQuad)

- Alopecia [*hair loss*] (Engerix-B, Recombivax, Twinrix)
- Ecchymoses [*subcutaneous bleeding*] (Engerix-B, Recombivax, Twinrix)
- Eczema (Engerix-B, Recombivax, Twinrix)
- Erythema [*skin redness*] (Fluarix, Infanrix, MMR-II, Pediarix, Pentacel, TDVAX)
- Erythema multiforme (Engerix-B, Fluad, Fluarix, Havrix, MMR-II, Pneumovax-23, ProQuad, Prevnar-13, Recombivax, Twinrix, Varivax)
- Erythema nodosum (Engerix-B, Recombivax, Twinrix)
- Exanthem [*widespread rash*] (Boostrix)
- Facial swelling/edema (Daptacel, Fluarix, MMR-II, ProQuad, Varivax)
- Hyperhydrosis [*abnormal sweating*] (Flulaval, Havrix, Twinrix)
- Impetigo (ProQuad, Varivax)
- Lichen planus [*inflammatory skin rash*] (Engerix-B, Twinrix)
- Panniculitis [*disease of fatty layer of skin*] (MMR-II, ProQuad)
- Parotitis [*inflammation of salivary glands*] (MMR-II, ProQuad)
- Pruritus [*itchy skin*] (ActHIB, Adacel, Afluria, Boostrix, Daptacel, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Infanrix, Kinrix, MMR-II, Prevnar-13, ProQuad, TDVAX, Tenivac)
- Purpura [*red/purple spots*] (Engerix-B, MMR-II, ProQuad)
- Rash (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Fluad, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ, Hiberix, Infanrix, IPV, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, TDVAX, Tenivac)
- Skin discoloration (Pentacel)
- Skin induration (MMR-II, ProQuad)
- Stevens-Johnson syndrome [*severe skin reaction*] (Engerix-B, Fluarix, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Varivax)
- Urticaria [*hives*] (ActHIB, Adacel, Afluria, Boostrix, DT, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, Recombivax, RotaTeq, Tenivac, Twinrix)
- Vesiculation (MMR-II)

#### Vascular disorders

- Cerebrovascular accident (ProQuad, Varivax)
- Flushing (Flulaval, FluzoneQ and FluzoneHD)
- Henoch-Schönlein purpura [*blood vessel inflammation*] (Boostrix, Fluarix, MMR-II, ProQuad, Varivax)
- Pallor (DT, Flulaval, Hiberix, Pediarix, Pentacel, Prevnar-13, Quadracel)
- Petechiae [*bleeding capillaries*] (Pediarix, Recombivax)
- Polyarteritis nodosa [*inflamed/damaged arteries*] (Recombivax)
- Renal vasculitis (Afluria, Fluad)
- Vasculitis [*blood vessel inflammation*] (Afluria, Engerix-B, Fluad, Fluarix, FluzoneQ and FluzoneHD, Havrix, MMR-II, Recombivax, Twinrix)

#### Urogenital disorders

- Epididymitis [*testicular inflammation*] (MMR-II, ProQuad)
- Orchitis [*inflammation of the testes*] (MMR-II, ProQuad)

273. In New York, under the current interpretation of the DOH regulation, if a child suffers any of the hundreds of serious adverse reactions above that are not highlighted, which are all conditions that the vaccine manufacturers include as reported vaccine adverse conditions, they

must continue to submit to immunization even if they suffer harm and even if they have a sibling or family member who died from that same adverse reaction to immunization.

***ACIP Doesn't Cover Most Harms Recognized by the VICP***

274. Similarly, the ACIP contraindications do not cover most of the harms proven and compensated by the United States Government as vaccine injuries.
275. Congress enacted the National Childhood Vaccine Injury Act of 1986 (the “1986 Act”) to grant pharmaceutical companies broad immunity, including complete financial immunity, from liability for injuries caused by vaccines.
276. The 1986 Act bars vaccine injured plaintiffs from suing in civil court and instead requires them to pursue redress through the National Vaccine Injury Compensation Program (VICP).
277. VICP requires plaintiffs to file a Petition with the United States Court of Federal Court of Claims within three years of the injury (regardless of whether the family knew or should have known the injury was caused by an immunization). The case is then litigated in a special proceeding with the US Department of Justice acting as opposing counsel on behalf of U.S. Health and Human Services (HHS).
278. Vaccine manufacturers make the only consumer products in the U.S. with this kind of immunity from liability. Even the partial immunities enjoyed by gun manufacturers pale in comparison.
279. The United States Supreme Court explained that Congress granted immunity to vaccine manufacturers because litigation costs from injuries and harm were becoming so high that the production of vaccines was no longer profitable. For example, for the DTP vaccine, “by the mid-1980’s...the remaining manufacturer estimated that its potential tort liability exceeded its annual sales by a factor of 200.” *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011).

280. Though the original intent of the VICP was to make the process easier for plaintiffs, subsequent changes have arguably made VICP proceedings more difficult and drawn out than civil proceedings. Plaintiffs in a VICP proceeding do not have discovery as of right and face many procedural barriers that do not exist in normal civil proceedings.

281. Despite the additional barriers and the fact that the maximum pay-out for death in any case is \$250,000, thousands of cases in the VICP have received awards, and HHS has paid out more than \$4.2 billion dollars to compensate victims since the inception of the program.

282. The following is a partial list of conditions that the VICP has compensated, where we highlight the two conditions also on the ACIP list of contraindications:

*Abscess, acute disseminated encephalomyelitis (ADEM), acute liver failure, adhesive capsulitis, aggravation of pre-existing encephalopathy, agoraphobia, anaphylactic shock, anaphylaxis, antisynthetase syndrome, angiomyoid fibrous histiocytoma, anxiety, aplastic anemia, arm injury, arthritis, ataxia, autism, autoimmune hep type 2, autoimmune hemolytic anemia, behavioral issues, bell's palsy, benign tumor, bilateral peripheral neuropathy, bilateral shoulder pain, bilateral symmetric diaphragmatic palsy, blindness, brachial neuritis, brachial plexopathy, brachial plexus neuritis, cardiac injury, celiac disease, cellulitis, cerebellitis, cerebellar ataxia, cerebrovascular accident, chest pain, choreiform movement disorder, chronic fatigue, chronic gastrointestinal issues, chronic arthritis, chronic inflammatory demyelinating polyneuropathy (CIDP), chronic urticarial, demyelinating disease of central nervous system, demyelinating polyradiculoneuropathy, chronic pain, complex regional pain syndrome, death, deltoid bursitis, demyelinating condition, demyelinating sensorimotor polyneuropathy, dermatomyositis, dravet syndrome, developmental delay, devic's disease, eczema, encephalitis, encephalopathy, epilepsy, epstein barr virus, erythema multiforme major, evan's syndrome, exacerbation of existing cardiomyopathy, expressive language delay, fatigue, fibromyalgia, frozen shoulder, gastrointestinal symptoms, gastroparesis, GM1 gangliosidosis, guillain-barre syndrome (GBS), headaches, hemophagocytic lymphohistiocytosis (HLH), hodgkin's lymphoma,*

*hypereosinophilia, hypersensitivity, hypotensive-hyporesponsive shock collapse (HHE), hypoproteinemia, hypotonia, immobile flaccid legs, immune issues, immune thrombocytopenia purpura, increased risk of cancer, infantile spasms, inflammatory arthritis, joint pain, juvenile dermatomyositis, juvenile idiopathic arthritis, juvenile rheumatoid arthritis (JRA), Kawasaki disease, keloid scarring, leukocytoclastic vasculitis (LCV), leukodystrophy, latent herpes simplex virus infection, lichen planus, lipomas, long thoracic nerve palsy, lupus (SLE), lymphangitis, lymphomatoid granulomatosis, macrophagic myofasciitis, meningoencephalitis, metal toxicity, mixed connective tissue disease (MCTD), monoplegia, multi organ failure, multiple sclerosis, muscle spasms, myalgias, myelitis, necrotizing pancreatitis, nerve damage, neurological injury, neuromyelitis optica (NMO), neuropathic arm pain, neuropathy, nodular fasciitis, opsoclonusmyoclonus syndrome (OMS), ocular visual disturbance, optic neuritis, panic overlap syndrome, panuveitis, panniculitis, parsonage turner syndrome, pemphigus vulgaris, peripheral neuropathy, permanent spastic tetraparesis, polyarthralgia, progressive encephalopathy, psoriatic arthritis, pulmonary edema, SIDS, radial nerve damage, rash, reactive inflammatory arthritis, reflex sympathetic dystrophy, residual seizure disorder (RSD), retro seizures, rhabdomyolysis, rheumatoid arthritis, rheumatologic injuries, scaring, sciula, seizures, seizure disorder, sensory neuropathy, sensory polyneuropathy, serum sickness, sirva, small fiber neuropathy, shoulder pain, splenic rupture, abscesses, strep infection, stroke, suprascapular neuropathy, syncope, synovitis, tendonitis, tendinopathy, toxic epidermal necrolysis (TEN), toxic shock syndrome, transverse myelitis (TM), thrombocytopenic purpura, ties, tremors, undifferentiated connective tissue disease (UCTD), urinary incontinence, uticarial angiodema, uveitis, vasculitis, vestibular neuritis*

283. Again, if a child suffered from any but two of the 100+ injuries listed above, the child would not qualify for a medical exemption under the challenged New York State medical exemption regulations. Instead, their parents would be forced to either give their child doses of the vaccines that could cause injury or death or forego the right to an education for their child. This is true even if the parents went to court to prove that the child's existing injury was

due to a vaccine. This is true even if the child has a sibling who had similar reactions and died.

***ACIP Doesn't Cover Most Harms Recognized by The Institutes of Medicine***

284. Similarly, the ACIP guidelines do not cover many of the harms recognized by the Institutes of Medicine in its comprehensive, congressionally directed reports and review of the scientific literature.

285. As part of the National Childhood Vaccine Injury Act of 1986, Congress directed HHS to contract with the Institute of Medicine (IOM) to evaluate and report on the adverse effects of federally recommended childhood vaccines.

286. Beginning in 1990, IOM appointed expert committees to review the evidence in the medical literature and from other sources on the safety of government-recommended and mandated childhood vaccines.

287. IOM published a series of reports between 1991 and 2013 evaluating all available scientific evidence related to certain reported vaccine injuries.

288. In these reports, the IOM concluded that the evidence supports a causal relationship between immunization and the following conditions:

- a.* Death
- b.* Thrombocytopenia
- c.* Chronic arthritis
- d.* Acute arthritis
- e.* Shock and unusual shock-like state
- f.* Protracted inconsolable crying
- g.* Acute encephalopathy (brain inflammation)
- h.* Chronic Nervous System Dysfunction (brain damage)
- i.* Anaphylaxis (whole-body allergic reaction)
- j.* Febrile Seizures (convulsions with fever)
- k.* Guillain-Barre Syndrome (peripheral nerve inflammation)
- l.* Brachial Neuritis (arm nerve inflammation)
- m.* Deltoid Bursitis (shoulder inflammation)

- n.* Acute & Chronic Arthritis (joint inflammation)
- o.* Syncope (sudden loss of consciousness/fainting)
- p.* Hypotonic/Hyporesponsive Episodes (shock and “unusual shock-like state”)
- q.* Protracted, Inconsolable Crying and Screaming
- r.* Vaccine Strain Infection (smallpox, live polio, measles, varicella zoster vaccines)
- s.* Hepatitis
- t.* Pneumonia
- u.* Meningitis

*See, e.g., <https://www.nap.edu/read/1815/chapter/2#7>;*

<https://www.nap.edu/read/2138/chapter/2#12>; <https://www.nap.edu/read/13164/chapter/2#3>;

<https://www.nap.edu/read/13563/chapter/9#130>

289. If a child or the child’s family member suffers one of the serious injuries causally related to vaccination, such as death, the ACIP guidelines do not allow that child to be exempt from subsequent doses.

290. Moreover, the IOM reports also stressed that there are hundreds of additional serious adverse reactions that cannot be ruled out even if the literature is not yet developed enough to prove that there is a causal link. In each of the reports from the 1990’s through 2013, the IOM concluded repeatedly that continuing significant gaps in scientific knowledge about the biological mechanisms of vaccine injury and death exist, necessitating additional research.

291. Since there are not enough methodologically sound epidemiological and biological-mechanism studies evaluating vaccine adverse events, the IOM committee acknowledged that it could not come to definitive conclusions – either supporting a causal relationship or refuting one – on causation for many of the reported vaccine reactions involving chronic brain and immune system dysfunction and death.

292. Specifically, the IOM found that for the then ten routinely used vaccines (MMR, DTaP, hepatitis B, hepatitis A, varicella zoster and meningococcal), there were too few scientifically

sound studies published in the medical literature to determine whether more than 100 serious brain and immune system problems are, or are not, caused by the vaccines, including multiple sclerosis, arthritis, lupus, stroke, SIDS, autism attention deficit syndrome, disruptive behavior disorder, tics and Tourette's syndrome, intellectual disability, allergy, atopy, autoimmunity, learning disorders, developmental disorders, and asthma.

293. The IOM reports discussed above have also consistently acknowledged evidence showing that there is individual susceptibility to serious vaccine injuries that will not show up in broader population studies.

294. The IOM concluded: "Finally, the committee found that evidence from assessments of health outcomes in potentially susceptible subpopulations of children who may have an increased risk of adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited...Most children who experience an adverse reaction to immunization have a preexisting susceptibility. Some predispositions may be detectible prior to vaccination; others, at least with current technology and practice, are not (IOM, 2012, p.82).

295. If a physician determines that a child's history of pre-existing conditions, family history or genetic evaluation puts her at risk of harm from one or more immunizations, a narrow adherence to ACIP guidance would not respect that conclusion, even though the IOM and countless peer-reviewed studies acknowledge that there may be an increased and individualized risk for that child of harm.

296. The New York regulations governing the medical exemption do contain a provision allowing a medical exemption if the determination about the risk of harm is based on ACIP *or* "any other evidence-based nationally recognized standard of care."

297. However, in practice, the defendants and their agents and assigns have failed to acknowledge or consider this category.

298. As science continues to develop, treating medical providers must receive deference when making recommendations; only they, rather than a school principal or outside consultant, have a full picture of the child's family, medical history, and potential risk factors.

**THE EMERGENCY REGULATIONS ALLOW NON-MEDICALLY TRAINED SCHOOL PRINCIPALS TO OVERRULE TREATING PHYSICIANS**

299. In addition to narrowing the definition that treating physicians may use to determine what "might be detrimental to a child's health", the new regulations allow school principals to substitute their own judgment about whether the risk is sufficient to allow for exemption and overrule treating physicians.

300. School principals are not generally medically trained or licensed to practice medicine.

301. Though it is not required that a principal base the decision to overrule a physician on any professional consultation, the NYSDOH does allow and encourage schools to seek a medical consultation from a third party – either a school district contracted physician or the NYSDOH itself.

302. However, before reaching a conclusion, the third-party reviewer is not required to examine the child or review the entire medical chart.

303. The third-party reviewer has no duty of care to the child, no obligation to consider the child's medical record or history, to contemplate the child's unique characteristics and genetic composition, or even to consider the opinion of the child's treating physician.

304. The third-party reviewer is not liable if the child is subsequently harmed as a direct result of her uninformed and incomplete medical opinion.

305. Allowing principals to overrule treating physicians based on the advice or opinion of non-treating physicians or other administrators is particularly problematic in that school principals are not medically trained.

306. Use of third-party reviewers deprives parents of the right to choose their own physician and severely limits their right to informed consent, as the third-party reviewer is not in communication with the parents or able to discuss the various health considerations at stake or the options.

307. Sometimes, the families are not even told whom the school consulted with or given any information about the basis for why that consultant decided to overrule their doctor.

308. In addition, there is an inherent conflict of interest as the third-party reviewers are employees of the entity that has a vested interest in ensuring a certain percentage of students attending school are fully vaccinated. They thus have a stake in reducing or eliminating the number of partially vaccinated or unvaccinated students.

309. Therefore, the third-party reviewer has an irreconcilable conflict of interest in providing a disinterested and fair recommendation regarding the risk to the individual child.

310. Sometimes, these conflicts are worse. Defendant Dr. Elizabeth Rauch-Phung, M.D., M.P.H. reviews many of the medical exemptions sent to the NYSDOH by local principals.

311. Since 2010, Dr. Rausch-Phung has served as the full time Director of the Bureau of Immunizations for the NYSDOH where she is the administrative physician.

312. Upon information and belief, Dr. Rausch-Phung has not seen or treated a patient for at least nine years.

313. Dr. Rausch-Phung typically issues advisory opinions to principals without reviewing the full medical records of the children, without meeting or speaking to the child, the family or the treating physician, and without any specialty in the various conditions that the medically fragile children have.

314. Dr. Rausch-Phung also has financial conflicts of interest.

315. Specifically, while holding her position, she participated in a promotional video paid for by Sanofi Pasteur, Inc. (“Sanofi”) to assist in increasing vaccine uptake and sales.

316. Sanofi is a pharmaceutical company with over \$5 billion in annual vaccine revenue, which sells a large portion of vaccines used in the United States, including the vaccines that Dr. Rausch-Phung is pushing on medically fragile children against their treating physician’s advice.

317. Dr. Rausch-Phung also serves as New York Program Manager for the Association of Immunization Managers (“AIM”), which received “critical support” from Merck, Sanofi and Pfizer, companies that together sell a majority of the vaccines mandated for children in the United States.

318. AIM, which is funded primarily by these vaccine manufacturers, specifically exists to increase vaccine uptake and sales.

319. Recognizing the clear conflict, federal employees involved in immunization activities are barred from active membership in this organization.

320. However, in New York, Dr. Rausch-Phung is not only an active member but program manager for the organization statewide.

321. Whether or not Dr. Rausch-Phung’s activities outside of the NYSDOH constitute a legal conflict of interest, it is the parents’ right to decide if they would prefer to choose a physician who has no such potential ethical conflict. It is also the parents’ right to decide whether Dr. Rausch-Phung is in the best position to evaluate the risks and benefits of various pharmaceutical products for their specific child given her lack of recent experience treating patients.

322. It is also the parents’ right to decide if they are comfortable with an evaluation done on a partial record without clinical examination or even review of the full medical record.

323. Parents should be free to choose their child's physician based on whom they believe is the most qualified and the best fit for their child.

324. The medical exemption exists precisely so that treating physicians, chosen by parents, can exercise clinical medical judgment, prevent harm, and protect medically vulnerable children when in their medical opinion, further vaccination may put the child at risk.

325. The medical exemption must remain under the full discretion of each treating physician to ensure that doctors can fulfill their duty to protect patients' health using evidence-based medicine while considering each individual patient's medical history.

**THE EMERGENCY REGULATIONS ARE OVERBURDEN SOME AND REQUIRE UNLAWFUL PRIVATE PATIENT INFORMATION AND DETAIL**

326. The Emergency Regulations also subject parents to overburdensome documentation requirements which unlawfully prevent many from exercising their right to a medical exemption and violate the children and family privacy rights.

327. Prior to 2019, it was enough for a physician to write a brief note indicating that a medically fragile child should be exempt from one or more of the immunizations due to the risk of harm and for indicating for how long. This was simple and within the scope of what doctors typically do on school forms.

328. Now, doctors are being asked to fill out extensive forms and lengthy accompanying letters which provide enough detail that any number of reviewers – none of whom is familiar with the child or their medical or family history and many of whom have no medical training at all – can understand how the physician arrived at their decision to certify an exemption and how that decision squarely fits into the ACIP guidelines.

329. Most doctors do not have the time or inclination to write such extensive reports as are required by the new regulations for something as routine as a school medical form.

330. Many doctors are also daunted by the hyper-legal nature of the reviews and though they understand the medical risks and reasons for their determination, are uncomfortable with trying to understand the legally narrowed criteria which now bind them.

331. Many families find themselves having to spend large amounts of money and time in consultation with attorneys, medical specialists, and doctors' offices to try to craft letters that will not be arbitrarily overruled.

332. This level of engagement and documentation makes it impossible for families without the means or influence to hire such teams to get the medical exemptions they deserve under law.

333. Moreover, the need for increased documentation creates significant privacy concerns.

334. Doctors are compelled to present extensive private health information and reasoning on their forms about the individual child and often family health histories.

335. These forms are then presented to school administrators who discuss and review this private information in detail with one another and with third party consultants and attorneys who, in some cases, affected families are not even allowed to know about. This presents a clear violation of medical privacy and HIPAA rights and is a dangerous precedent to set.

336. Subparagraph (ii) of paragraph (4) of subdivision (c) of section 66-1.2 further requires that a doctor submit the entire exemption request, including the extensive medical history and personal information now required on exemption forms to withstand scrutiny, into the New York State Immunization Information System.

337. Even for conditions that are listed as permanent contraindications, the families must obtain a new form every year, adding expense and burden to the already burdened families and treating physicians.

338. A yearly submission also means that families must subject themselves to annual uncertainty as to whether their child will be allowed to stay in school.

339. Many schools accept children initially but then, months later, expel them with a week's notice mid-year.

340. Treating physicians have been threatened and confused by the new regulations to the extent that many are hesitant to write exemptions even where they believe that one or more immunization may be detrimental to a patient's health and that the grounds does fit within the ACIP criteria.

341. The NYSDOH has indicated that its staff will be monitoring physicians who write medical exemptions and have been investigating and intimidating physicians who do so.

342. Many parents have been told by their treating specialists and physicians that, though the physician believes that the child could be harmed by an immunization, s/he cannot dedicate the time and resources it takes to draft such an exemption.

343. Many other physicians are confused by what the new regulations mean and do not want to risk any backlash from the NYSDOH if there is disagreement.

344. Many doctors that wrote medical exemptions last year and for many previous years are telling plaintiffs that they are not willing to undergo the same burdens and scrutiny again this year.

345. Local Health Departments have given physicians false information about how narrow the criteria are, and many physicians have reported being bullied and threatened by the NYSDOH or the school district contract physicians.

346. For those lucky few children whose physicians do submit themselves to this onerous process, upon the advice and pressure from defendant DOH, school principals are overruling the vast majority of medical exemptions.

347. Since the passage of the “emergency” regulations last year, an alarming number of medically fragile children have been expelled from school and denied services when they refused to immunize their children against medical advice.

**MANY MANDATORY VACCINES ONLY PROTECT THE RECIPIENT**

348. At least half of the vaccines that are on the mandatory schedule in New York are only able to provide protection to the recipient and are not able to provide any protection for the rest of the community.

349. Tetanus is not a contagious disease. Tetanus containing vaccines cannot protect anyone but the recipient of the vaccine.

350. The polio vaccine mandated in the United States— the inactivated polio vaccine (“IPV”)— does not stop replication and transmission and allows the recipient to become an asymptomatic carrier and pass polio on to others.

351. The same is true of the vaccines for pertussis, diphtheria, and meningococcal infection.

352. Other vaccines on the list, particularly the live vaccines, are generally thought to be able to protect against replication and transmission. However, they have also been shown to cause recently vaccinated individuals to shed and infect others. For this reason, cancer patients are often told to stay away from the recently vaccinated.

353. The number of medically fragile children seeking a medical exemption in New York and the risk to the community from them if they forego immunizations on the advice of their

physicians is small enough that there is no compelling reason to narrow the scope of the medical exemption or place these burdens on it.

354. Hundreds of vulnerable children have suffered irreparable harm as the result of the policies, procedures, and practices adopted by the defendants regarding the medical exemption.

### **CLAIMS FOR RELIEF**

#### **FIRST CLAIM FOR RELIEF**

##### **Violations of Substantive Due Process Rights**

355. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

356. The Constitution of the United States of America recognizes and preserves the right of citizens to be free from government actions that harm life, liberty, and property. These inherent and inalienable rights reflect the basic societal contract of the Constitution to protect people from government infringement on basic natural rights and freedoms.

357. Defendants have violated and continue to violate these fundamental rights by promulgating and enforcing regulations and practices which place arbitrary and capricious limitations on the availability of a medical exemption from immunization.

358. These actions are putting medically fragile children at risk of harm and death and thereby infringing upon their fundamental right to life itself.

359. Defendants' practice of overruling, or permitting the overruling of the judgment of medical doctors familiar with plaintiffs' children by persons unqualified to make such judgments, depriving these children of a free public education (and the right to pursue any education at all), and depriving them of federally guaranteed services unless they incur the risk of substantial injury and/or death, is conscious-shocking and irrational and violates the

plaintiffs' right to substantive due process as guaranteed by the Fourteenth Amendment and made actionable by 42 U.S.C. section 1983.

**SECOND CLAIM FOR RELIEF**  
**Violation of 14<sup>th</sup> Amendment by burdening liberty interest in parenting**

360. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

361. Parents have a well-recognized liberty interest in directing the care and upbringing of their children. This includes choosing the most appropriate treating physician and choosing whether to follow their advice when the physician has determined that their child could be at risk of harm from one or more immunization.

362. Defendants' practice of overruling, or permitting the overruling of the judgment of licensed medical doctors, chosen by parents and familiar with plaintiffs' children by persons unqualified to make such judgments, trespasses upon plaintiffs' right as parents to make decisions concerning the health and welfare of their children, one central element of liberty as guaranteed by the Fourteenth Amendment and made actionable by 42 U.S.C. section 1983.

363. The plaintiffs' fundamental rights and liberty interests are being unconstitutionally infringed upon.

364. The defendants' practices, policies and procedures adopted in relation to implementation of the regulations regarding medical exemptions to immunization in New York are not narrowly tailored to serve a compelling state interest.

365. Many of the practices and burdens serve no rational basis at all.

**THIRD CLAIM FOR RELIEF**

**Violation of 14<sup>th</sup> Amendment by burdening liberty interest in informed consent**

366. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

367. The right of informed consent is protected by the Constitution of the United States, the Treaties and Laws made pursuant thereto, and the case law of the United States of America.

368. Parents have a fundamental right and liberty interest to be able to exercise informed consent on behalf of their minor children in accordance with the medical advice received from their licensed physicians.

369. Directly and through their agents, defendants have willfully refused to reasonably accommodate the fundamental right of parents, thereby placing an undue burden on the protected interests and rights of the Plaintiffs to exercise informed consent and opt out of a medical intervention which has been established to be potentially harmful to the individual child.

370. Not only are parents denied the discretion about whether to consent to treatment in accordance with the recommendation of their licensed physician, but even the right to basic information has been taken away. Determinations are being made between school principals and outside doctors or consultants who are not in communication with the parents and children and who do not provide a full explanation of the risks and benefits of the procedures as it applies to the child.

**FOURTH CLAIM FOR RELIEF**

**Violation of 14<sup>th</sup> Amendment by burdening minors' right to free public education**

371. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

372. Children have a liberty interest in being allowed to pursue an education generally and the right, under the New York State Constitution and the United States Constitution, to a free public education.

373. Defendants' practice of conditioning children's right to pursue an education, public, private or daycare, or receive guaranteed benefits, on the parents' waiver of fundamental rights including the right to exercise informed consent in furtherance of the best interests of their child based on the advice of licensed physicians, violates the doctrine of unconstitutional conditioning.

**FIFTH CLAIM FOR RELIEF**  
**Violation of Rehabilitation Act of 1973**

374. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

375. The new regulations and the defendants' policies, practices, and procedures in implementing them are not narrowly tailored and both facially and in practice result in overbroad application and infringement upon the plaintiffs' fundamental rights.

376. Plaintiff children are all disabled as defined by the Rehabilitation Act of 1973 in that each of them suffers from a limitation in the performance of one or more major life activity.

377. By dint of their manner of administering the medical exemption provided by the State of New York, defendants have unlawfully excluded plaintiffs' children from participation in an activity, namely schooling, which receives federal financial assistance, thereby violating section 504 of the Rehabilitation Act of 1973.

**SIXTH CLAIM FOR RELIEF**  
**Violation of Rehabilitation Act of 1973**

378. Plaintiffs hereby re-allege and incorporate by reference each of the allegations set forth above.

379. Medically fragile children are being disparately impacted by the state's narrow and arbitrary medical exemption requirements.

380. The ACIP guidelines are not meant to be comprehensive and do not cover reasons why some children might be put at risk by one or more of the mandated immunizations.

381. Medically fragile sub-populations particularly have not been adequately studied, and there is significant divergence of thought within the medical and scientific community about the risk that is posed to medically fragile subpopulations.

382. The challenged regulatory scheme cannot be defended as a law of general applicability.

383. There is no rational basis for discriminating against children who suffer from the hundreds of recognized harms that do not fall on the ACIP contraindications and precautions list.

384. Defendants have violated the rights of medically fragile children to receive equal protection of the law by enacting and promulgating regulations which disparately impact medically fragile children.

385. Plaintiffs are being harmed by the actions of the Defendants in the violations of all the above-named causes of action.

386. Wherefore, Plaintiffs pray for relief as more fully set forth below.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiffs pray that this Honorable Court accept jurisdiction in this matter and:

- A. Certify plaintiffs as class representatives of a class comprised of persons/children who have been sought medical exemptions in New York State since August 1, 2019;

- B. Recognize Michael Sussman, Esq., Sujata Gibson, Esq., Robert F. Kennedy, Jr., Esq. and Mary Holland, Esq., as counsel for the class;
- C. Declare that Defendants have violated the constitutional rights of the plaintiffs and Section 504 of the Rehabilitation Act;
- D. Declare that the NYSDOH regulations restricting the availability of the medical exemption are facially unconstitutional and unconstitutional as applied;
- E. Permanently enjoin defendants from subjecting the Named Plaintiffs and Plaintiff class to policies and practices that violate their constitutional and other legal rights including specifically enjoining defendants from engaging in the following practices:
  - [1] allowing school district administrators to deny requests for medical exemptions submitted on behalf of class members by physicians licensed to practice in the State of New York or primary care Nurse Practitioners or Physician's Assistants; [2] requiring that as a condition for obtaining medical exemptions, class members provide detailed medical information which trespasses class members right to privacy of medical records to the extent consistent with their request for a medical exemption; [3] requiring annual recertification of medical exemptions unless the treating provider indicated it was a temporary exemption; [4] predefining the medical conditions which may predicate grant of a medical exemption rather than allowing licensed physician chosen by the parents to make clinical determinations about what may cause harm;
- F. Order defendants to develop, adopt and implement policies and practices to ensure that the State of New York and it's school districts do not continue to engage in burdensome reviews of medical exemptions or deny medically fragile children an

education for opting out of one or more mandatory school vaccine when their licensed physician has certified that it may be harmful to their health;

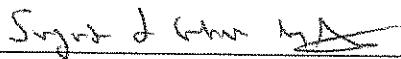
G. Temporarily enjoin defendants from excluding children from school who have submitted a medical exemption to immunization signed by a licensed physician or treating nurse practitioner; and

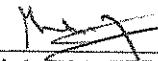
H. Award plaintiffs' reasonable costs and attorney's fees incurred in this action; and

I. Grant any such other relief as the Court deems just, necessary, and proper.

Dated: June 22, 2020

Respectfully submitted,

  
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